

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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EISAI CO., LTD. and EISAI INC.,

Plaintiffs,

-v.-

DR. REDDY'S LABORATORIES, LTD.,  
DR. REDDY'S LABORATORIES, INC.,

Defendants.  
-----X

03 Civ. 9053 (GEL)

**OPINION AND ORDER**

**FINDINGS OF FACT  
AND CONCLUSIONS OF LAW**

EISAI CO., LTD. and EISAI INC.,

Plaintiffs,

-v.-

TEVA PHARMACEUTICALS USA, INC.,

Defendant.  
-----X

03 Civ. 9223 (GEL)

Joseph M. O'Malley, Bruce M. Wexler, David M.  
Conca, and Gary Ji, Paul, Hastings, Janofsky &  
Walker LLP, New York, NY; David B. Tulchin,  
James T. Williams, and Niall D. O'Murchadha,  
Sullivan & Cromwell LLP, New York, NY,  
for Plaintiffs.

Maurice B. Ross, Louis H. Weinstein, Ellen T.  
Lowenthal, Nathaniel I. Watts, Budd Larner, P.C.,  
Short Hills, NJ, for Defendants Dr. Reddy's  
Laboratories, Ltd. and Dr. Reddy's Laboratories Inc.

David M. Hashmall, Frederick H. Rein, and Elaine  
Herrmann Blais, Goodwin Proctor LLP, New York,  
NY, for Defendant Teva Pharmaceuticals USA, Inc.

GERARD E. LYNCH, District Judge:

In this patent infringement action brought by plaintiffs Eisai Co., Ltd. and Eisai Inc. (collectively, “Eisai”) against defendants Dr. Reddy’s Laboratories, Ltd., and Dr. Reddy’s Laboratories, Inc. (collectively, “Reddy”), and Teva Pharmaceuticals USA, Inc. (“Teva”), defendants maintain that Eisai’s patent should not be enforced because Eisai engaged in inequitable conduct before the U.S. Patent and Trademark Office (“PTO”) in prosecuting the patent. The case having been tried to the Court without a jury, the Court concludes that defendants have failed to prove inequitable conduct by clear and convincing evidence, and that plaintiffs accordingly have established their claim of patent infringement.

The following constitutes the Court’s findings of fact and conclusions of law, in accordance with Rule 52(a), Fed. R. Civ. P. To the extent any finding of fact reflects a legal conclusion, it shall to that extent be deemed a conclusion of law, and vice versa.

## **FINDINGS OF FACT<sup>1</sup>**

### **I. The Parties**

1. Eisai Co., Ltd. is a corporation incorporated and existing under the laws of Japan, and has its principal place of business at 4-6-10 Koishikawa, Bunkyo-ku, Tokyo 112-8088, Japan. (Statement of Agreed Facts ¶ 1.)

2. Eisai Inc. is a United States subsidiary of Eisai Co., Ltd., and a corporation incorporated under the laws of the State of Delaware, and has its principal place of business at

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<sup>1</sup> The Court makes these findings of fact based on the evidence of record, reasonable inferences drawn therefrom, assessment of credibility and demeanor, and resolution of any conflicts in the evidence. Citations to exhibits and testimonial evidence indicate some but not necessarily all of the direct evidence pertaining to a given finding.

100 Tice Boulevard, Woodcliff Lake, NJ 07677. (Id. ¶ 2.)

3. Dr. Reddy's Laboratories, Ltd., is a public limited liability company incorporated and existing under the laws of India and having a principal place of business at 7-1-27, Ameerpet, Hyderabad, 500 016, India. (Id. ¶ 4.)

4. Dr. Reddy's Laboratories, Inc., is a corporation incorporated under the laws of the State of New Jersey, having its principal place of business at 200 Somerset Corporation Blvd., 22 West, Bldg. 2, 7th Floor, Bridgewater, NJ 08807. (Id. ¶ 5.) It is a subsidiary of Dr. Reddy's Laboratories, Ltd., and the exclusive agent in North America for Dr. Reddy's Laboratories, Ltd. (Id. ¶¶ 6-7.)

5. Teva Pharmaceuticals USA, Inc. ("Teva USA"), is a corporation organized under the laws of the State of Delaware, having its corporate headquarters and principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. (Id. ¶ 8.)

6. Teva USA is a wholly-owned subsidiary of Orvet-UK Ltd. Holding, which is a wholly-owned subsidiary of Teva Pharmaceuticals Europe (Holland), which is wholly-owned by Teva Pharmaceutical Industries, Ltd. (Id. ¶ 9.)

## **II. Jurisdiction and Venue**

7. Reddy does business in this District and in other jurisdictions in the United States, and this Court has personal jurisdiction over it. (Id. ¶ 10.)

8. Teva sells products and does business in this district and in other jurisdictions in the United States, and this Court has personal jurisdiction over it. (Id. ¶ 11.)

9. Eisai's action against Reddy and Teva arises under the patent laws of the United States of America, and this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and

1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b). (*Id.* ¶ 12.)

10. Reddy and Teva counterclaim against Eisai for declaratory judgment pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. The basis for declaratory judgment is an actual controversy arising under the United States patent laws, Title 35 of the United States Code, and the complaint in this action regarding U.S. Patent No. 5,045,552 (“the ’552 patent”). This Court has jurisdiction over Reddy and Teva’s claims pursuant to 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b), (c) and 1400(b) and under the Drug Price and Patent Term Restoration Act (“Hatch-Waxman Act”). (*Id.* ¶ 13.)

### **III. Nature of the Action and Procedural History**

11. The Hatch-Waxman Act, 21 U.S.C. § 355 and 35 U.S.C. § 271(e) (1994) (codified as amended), permits would-be manufacturers of generic versions of an already approved, patented drug to seek expedited approval from the Food and Drug Administration (“FDA”) before expiration of the patent, by means of an Abbreviated New Drug Application (“ANDA”). *See Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1342 (Fed. Cir. 2000). The filing of an ANDA for a drug claimed in a patent constitutes a legally cognizable act of infringement for which the owner of the patent may bring suit under 35 U.S.C. § 271(e)(2). *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1344 (Fed. Cir. 2004); *see Eisai Co. v. Dr. Reddy’s Laboratories* (“*Eisai I*”), 472 F. Supp. 2d 493, 494 (S.D.N.Y. 2006).

12. Eisai Co., Ltd., is a pharmaceutical company and is the owner of the ’552 patent, which claims the chemical compound rabeprazole sodium. Eisai Inc. is a pharmaceutical company and is the exclusive licensee of the ’552 patent in the United States. (Statement of

Agreed Facts, ¶¶ 14-17.)

13. Rabeprazole sodium<sup>2</sup> is the active ingredient in Eisai's drug product Aciphex. Aciphex, produced by Eisai, is a proton pump inhibitor that suppresses acid production in the cells of the stomach lining. (Id. ¶¶ 18-19.)

14. In 1999, Aciphex was approved by the FDA for the healing of erosive gastroesophageal reflux disease ("GERD"), maintenance of healed erosive GERD, healing of duodenal ulcers and treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome. Aciphex is also approved for treatment of daytime and nighttime heartburn and other symptoms associated with GERD. (Id. ¶ 20.)

15. Aciphex is sold in several countries and has had U.S. sales reported at list price of over \$1 billion per year. (Id. ¶ 21.)

16. In August 2003, Reddy filed with the FDA an ANDA containing a paragraph IV certification<sup>3</sup> with respect to the '552 patent under 21 U.S.C. § 505(j)(2)(B)(ii) of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 355) seeking approval to market a generic rabeprazole product before the expiration of the '552 patent. (Id. ¶ 22.)

17. In August 2003, Teva filed in the FDA an ANDA containing a paragraph IV certification with respect to the '552 patent under 21 U.S.C. § 505(j)(2)(B)(ii) of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 355) seeking approval to market a generic

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<sup>2</sup> For purposes of this litigation, the Court and parties generally refer to both rabeprazole and rabeprazole sodium as "rabeprazole."

<sup>3</sup> A "paragraph IV certification" is so known for the statutory subsection, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that provides for its filing by those seeking expedited FDA approval of a generic drug, to address the patent status of the already approved drug of interest. See Eisai I, 472 F.Supp.2d at 504.

rabeprazole product before the expiration of the '552 patent. (Id. ¶ 23.)

18. By letter dated October 15, 2003, Reddy sent a notice to Eisai in which Reddy represented that it had filed an ANDA for rabeprazole sodium, including the certification with respect to the '552 patent, and that it sought approval of its ANDA prior to the expiration of that patent. Eisai received notice of the certification. (Id. ¶ 24.)

19. By letter dated October 8, 2003, Teva sent a notice to Eisai in which Teva represented that it had filed an ANDA for rabeprazole sodium, including the certification with respect to the '552 patent, and that it sought approval of its ANDA prior to the expiration of that patent. Eisai received notice of the certification. (Id. ¶ 25.)

20. On November 17, 2003, Eisai filed suit for patent infringement against Reddy, Civil Action No. 03 Civ. 9053.

21. On November 20, 2003, Eisai filed suit for patent infringement against Teva, Civil Action No. 03 Civ. 9223.<sup>4</sup>

22. In defense of this claim, Reddy and Teva have alleged, among other things, that Eisai's '552 patent is unenforceable because of Eisai's inequitable conduct before the PTO during prosecution of the patent. (Reddy's Fourth Amended Answer and Counterclaims; Teva's Third Amended Answer and Counterclaims.)

23. By Stipulation and Order dated June 23, 2004 (Plaintiff's Trial Exhibit ("PTX") 23), Reddy stipulated that "Claims 1-6 of the ['552 patent] are valid" and that the rabeprazole sodium

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<sup>4</sup> A third generic company, Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc., also filed an ANDA and a paragraph IV certification. Eisai brought suit against Mylan on January 28, 2004, No. 04 Civ. 656. Mylan stipulated to be bound by the outcome of the Teva and Reddy proceedings rather than litigate. (Stipulation and Order dated November 3, 2004, Doc. # 23).

tablets described in Reddy's ANDA infringe all enforceable claims of the '552 patent.

24. Through its counsel, Teva conceded infringement of Claims 1-6 of the '552 patent on September 3, 2004. (PTX 24.)

25. On November 22, 2005, Eisai filed a motion for summary judgment of patent validity with respect to Teva, which was granted on October 5, 2006. See Eisai Co. v. Teva Pharmaceuticals ("Eisai II"), No. 03 Civ. 9223 (GEL), 2006 WL 2872615 (S.D.N.Y. Oct. 6, 2006).

26. On November 22, 2005, Eisai also filed a motion for summary judgment of no inequitable conduct with respect to both Teva and Reddy. In a separate Opinion and Order also dated October 5, 2006, the Court granted Eisai's motion in part and denied it in part. See Eisai I, 472 F. Supp. 2d 493.

27. Following the Court's summary judgment ruling, Teva and Reddy advised the Court by letter dated November 22, 2006, that they would not pursue certain previously-alleged inequitable conduct allegations arising out of comparisons of rabeprazole to omeprazole made during the prosecution of the '552 application. By order dated November 29, 2006, the Court dismissed with prejudice Teva's and Reddy's inequitable conduct allegations relating to comparisons of rabeprazole with omeprazole.

28. As a result of the various admissions by defendants and the Court's prior summary judgment rulings, only defendants' affirmative defense of inequitable conduct remains in the case. With regard to this defense, three allegations remained for trial:

(a) Whether Eisai committed inequitable conduct in the failure to disclose the existence of, and/or certain developments relating to, a later-filed, later-issuing co-pending

patent application;

(b) Whether Eisai committed inequitable conduct in failing to disclose the patent reference, Byk Gulden WO 8602646;

(c) Whether Eisai committed inequitable conduct in selecting the data it included in a Rule 132 Declaration filed in the prosecution of the '552 application data.

29. From March 5, 2007, through March 14, 2007, trial was held regarding these remaining allegations. The agreed record of the trial consists of the trial transcript, the direct testimony affidavits of those witnesses who presented testimony in this fashion (as modified by occasional Court rulings striking portions of such testimony), a volume of deposition excerpts identifying those portions of deposition testimony admitted by stipulation as trial evidence (Court Exhibit ("CX") 1), and those documents received in evidence (identified on a list stipulated by the parties, CX 2).

#### **IV. Background on Certain Proton Pump-Inhibiting Compounds**

30. In the late 1980s it was believed that peptic ulcers – i.e., localized erosions of the mucous membrane of the duodenum or stomach – were caused by an imbalance between “offensive” factors such as gastric acid or pepsin, and “defensive” factors such as resistance of the mucous membrane, mucilage secretion, bloodstream or control of the duodenum. (PTX 1, '552 patent, col. 1, lines 15-24.)

31. In the late 1970s and early 1980s, it was discovered that the stomach's parietal cell contained an enzyme, called “H+K+ATPase,” which was responsible for the production of acid in the stomach. (Statement of Agreed Facts ¶ 26.)

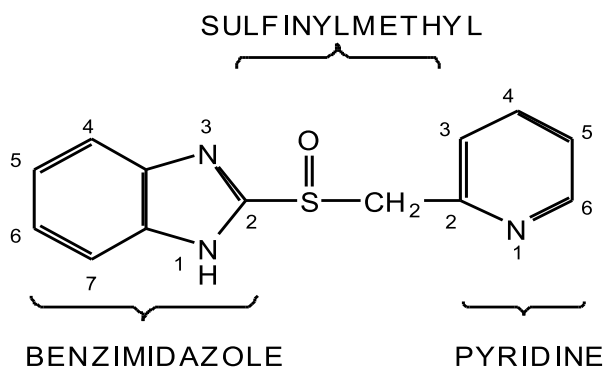


32. The H+K+ATPase enzyme became known as the “proton pump,” referring to the fact that it pumped protons (H<sup>+</sup> ions) into the stomach which would combine with chloride ions (Cl<sup>-</sup>) to form hydrochloric acid (HCl), otherwise known as gastric acid. (Id. ¶ 27.)

33. A “proton pump inhibitor” (“PPI”) inhibits the activity of this enzyme. (Id. ¶ 28; Forte Aff. ¶¶ 11-12.) PPIs are useful in treating peptic ulcers and related symptoms by inhibiting secretion of gastric acid in the stomach. (Forte Aff. ¶¶ 11-12.) At the time Eisai scientists were working on the development of rabeprazole, the precise chemical mechanisms by which PPI’s operated to inhibit the activity of H+K+ATPase, and indeed the precise chemical structure of the enzyme, were poorly understood. (DTX 87T at ECL 120499; 3/14/07 Tr. 982:17-988:3.)

34. In 1985, A. Brändström, P. Lindberg, and U. Junggren, scientists working for the Swedish company AB Hässle (“Hässle” or “Astra”) – later known as Astra AB and today known as AstraZeneca AB – published an article describing a class of compounds that act as inhibitors of gastric acid secretion, “*Structure Activity Relationships of Substituted Benzimidazoles*,” 20 (Supp. 108) Scandinavian J. of Gastroenterology, pp. 15-22 (1985) (the “Brändström article”). (DTX 1022; LaVoie Aff. ¶ 21; Cooperman Aff. ¶ 10.)

35. The Brändström article disclosed a class of compounds that are chemically-named “benzimidazole-sulfinylmethyl-pyridine” and have the following skeletal structure (the “Brändström core structure”) :



(DTX 1022; LaVoie Aff. ¶ 21; Cooperman Aff. ¶ 11). The Brändström article characterized the Brändström core structure as the “[t]he simplest structural fragment necessary for activity.” (Id.).

36. By convention, each atom of the pyridine ring in this basic core structure is numbered, as indicated in the diagram above (DTX 1022; LaVoie Aff. ¶ 21; Cooperman Aff. ¶ 12). Each of carbon atoms 3, 4, 5 and 6 on the pyridine ring can be bonded to a hydrogen (which is often omitted from the structure drawing) or a non-hydrogen substituent. (Id.)

37. Persons of ordinary skill in the art would have been led by the Brändström article to focus on the substituents to the pyridine ring, because the article concluded that “pyridine substitution is essential to the [pharmacological] effect” of the compound.<sup>5</sup> (DTX 1022 at 22;

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<sup>5</sup> Eisai and Teva agreed, for purposes of Eisai’s motion for summary judgment of patent validity, that that the person of ordinary skill in the art at the relevant time should be defined as “hav[ing] a graduate degree in one of the fields of medicinal chemistry, pharmacology, organic chemistry,

LaVoie Aff. ¶ 21). In the figure above, medical chemists would understand that a hydrogen atom (H) is attached at each of positions 3, 4, 5, and 6 on the pyridine ring and at each of positions 4, 5, 6, and 7 on the benzimidazole ring, even though they are not shown. (LaVoie Aff. ¶ 21; Cooperman Aff. ¶ 12.) Positions where only hydrogen atoms are attached are considered “unsubstituted.” Any non-hydrogen chemical group attached to any of the positions would be considered a “substituent.” Position 2 on the pyridine ring cannot have any substituent as it is already connected to the CH<sub>2</sub> group of the bridge which connects the pyridine ring to the rest of the compound. (LaVoie Aff. ¶ 21.)

38. The '552 patent notes that a “wide variety of compounds having a benzimidazole structure have been proposed,” and that one of them in particular – called “omeprazole” – was under active development and was then the most promising. (Statement of Agreed Facts ¶ 29.)

39. The compounds discussed in this litigation are substituted at the 4- position of the pyridine ring with “alkoxy” or “alkoxyalkoxy” substituents. Alkoxy substituents are more specifically named according to the number of carbons present in the chain. (LaVoie Aff. ¶ 47; Cooperman Aff. ¶ 13.)

40. For example, an alkoxy substituent with only one carbon in the chain is referred to as a “methoxy” substituent, an alkoxy with two carbons is an “ethoxy” substituent, and one with three carbons in the chain is referred to as a “propoxy” substituent. (Id.)

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biochemistry, or pharmaceutical chemistry, and . . . practical experience in an academic or industrial laboratory.” They agreed that the person would also have collaborated extensively with those in the referenced fields other than her own, thus becoming knowledgeable in those fields, and that she also would have learned about patent protection of pharmaceuticals. See Eisai II, 2006 WL 2872615 at \*4. As the substance of the art and the disputed claims remain the same, and no party has since objected or suggested a competing definition, the Court adopts the earlier-stipulated definition for purposes of resolving the issues at trial.

41. An “alkoxyalkoxy” substituent is one in which two alkoxy groups are connected in sequence. (*Id.*)

42. Alkoxyalkoxy substituents are named according to the specific alkoxy segments of which they are comprised.

Nomenclature	# carbons	Chemical structure
Methoxy	1	-OCH <sub>3</sub>
Ethoxy	2	-OCH <sub>2</sub> CH <sub>3</sub>
Propoxy	3	-OCH <sub>2</sub> CH <sub>2</sub> CH <sub>3</sub>
Methoxyethoxy	1,2	-OCH <sub>2</sub> CH <sub>2</sub> -OCH <sub>3</sub>
Methoxypropoxy	1,3	-OCH <sub>2</sub> CH <sub>2</sub> CH <sub>2</sub> -OCH <sub>3</sub>

(Cooperman Aff. ¶13.)

43. A compound with a substituent at the 4-position of the pyridine ring and with either (a) non-hydrogen substitution at both the 3- and 5-positions of the pyridine ring or (b) hydrogen substitution at both the 3- and 5-positions of the pyridine ring has been referred to in this litigation as “symmetrically substituted,” because there is symmetry of substitution around the 4-position. In contrast, a compound with a non-hydrogen substituent either at the 3- or 5-position (but not at both) has been referred to in this litigation as “asymmetrically substituted.” (LaVoie Aff. ¶¶ 23-25.)

44. Omeprazole, which was created by Hässle, was the first compound commercially marketed to inhibit acid secretion by the mechanism of inhibiting the H<sup>+</sup>K<sup>+</sup>ATPase enzyme. (Statement of Agreed Facts ¶ 30.)

45. Hässle obtained U.S. Patent No. 4,255,431 (“the Junggren ’431 patent,” or, collectively with two other Hässle patents, “Junggren”) in 1981,<sup>6</sup> claiming a genus of compounds

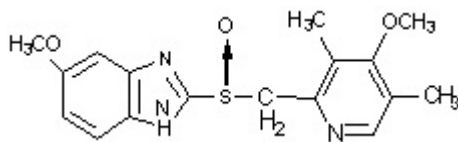
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<sup>6</sup> There are actually three patents referred to by the parties as Junggren, *see* DTX 101 at DRLRAB 274, and which uncontestedly may be treated as one for purposes of this case.

having the Brändstöm core structure depicted above. (Id. ¶ 31; DTX 101 at DRLRAB 274-75.)

46. Omeprazole is identified as Example 23 in Table 1 of the Junggren '431 patent.

Omeprazole has the following structure, which is depicted in the '552 patent at column 1, lines 50-55.



(Statement of Agreed Facts ¶¶ 32-33.)

47. The Junggren '431 patent claimed compounds in which the alkoxy or alkoxyalkoxy substituent on the 4-position of the pyridine ring substituent could be a methoxy, ethoxy, methoxyethoxy or ethoxyethoxy. (DTX 101 at DRLRAB 284, col. 14:25-48.)

48. The Junggren '431 patent does not cover rabeprazole or any other compound with a methoxypropoxy substituent at the 4-position of the pyridine ring. The Junggren '431 patent specifically discloses an example of a symmetric compound having methoxyethoxy at the 4-position of the pyridine ring. This compound is example 27 of Table 1 in the Junggren '431 patent ("Example 27 "). (Id. at DRLRAB 282, col. 9).

49. The German pharmaceutical company Byk Gulden was also involved in research and development regarding compounds having the Brändström core structure. On May 9, 1986, Byk Gulden's international patent application No. PCT/EP85/00575 was published in German as WO 86/02646 ("Byk Gulden '646," or simply, "Byk Gulden"). (DTX 1035.) The English counterpart of Byk Gulden issued on August 11, 1987. (DTX 1037.)

50. Byk Gulden generically describes a massive number of possible compounds. It depicts a chemical structure with 10 sites of potential substitution and describes a genus encompassing over 30 billion possible combinations of substituents. Despite the vast possibilities for variation, the claims of Byk Gulden require the presence of fluorinated alkoxy substituents on the benzimidazole ring. Every working example described in the patent, and each of the more than 80 compounds specifically disclosed, has certain fluorine substituents on the benzimidazole ring. The only pharmacology data provided in Byk Gulden relates to compounds having fluorinated alkoxy substituents on the benzimidazole ring. A review of Byk Gulden reveals that these fluorinated alkoxy substituents on the benzimidazole ring are not a minor feature, but rather a critical teaching of the reference. (See DTX 1035; Hopfinger Aff. ¶ 48, 75.)

51. Among Byk Gulden's approximately 80 specifically disclosed compounds with fluorinated alkoxy substituents on the benzimidazole ring, four also feature asymmetrical substitution at the pyridine ring, with a 3-position methyl, a 4-position methoxyethoxy, and no substitution at the 5-position. (DTX 1035 at DRLRAB 4135, lns. 1-2, DRLRAB 4136, lns. 29-30, DRLRAB 4137, lns. 8-9, DRLRAB 4138, lns. 36-37; see also DTX 103, '013 application, at DRLRAB 2631.)

52. Defendants contend that Byk Gulden specifically teaches compounds with methoxypropoxy substituents at the 4-position of the pyridine ring. (LaVoie Aff. ¶ 29, 48-52.) Plaintiff's expert, Hopfinger, far more credibly explained that Byk Gulden does not contain such a teaching. Although the Byk Gulden patent at one point specifically identifies methoxypropoxy as an example of an alkoxyalkoxy substituent that could be selected as a 4-position pyridine ring

substituent (DTX 1035 at DRLRAB 4117, 4119), it does so in the course of broadly describing a genus encompassing a possible 30 billion compounds. (Hopfinger Aff. ¶¶ 61-75.) This calculation is not challenged by defendants. There is no mention or appearance of a methoxypropoxy substituent anywhere on the molecule of any of the specifically disclosed compounds listed in Byk Gulden, in any of the working examples, or among any of the compounds for which the patent provides pharmacological data. The Court agrees with Hopfinger that the one mention of methoxypropoxy in Byk Gulden appears in a “genus . . . so enormous, [that] it is not a teaching of the structure of any particular compound. In fact the genus is so broad, it provides absolutely no information to a practicing medical chemist.” Byk Gulden does not teach any compound having a methoxypropoxy substituent at the 4-position of the pyridine ring. (*Id.*)

**V. The Invention of the Compound Claimed in the '552 Patent**

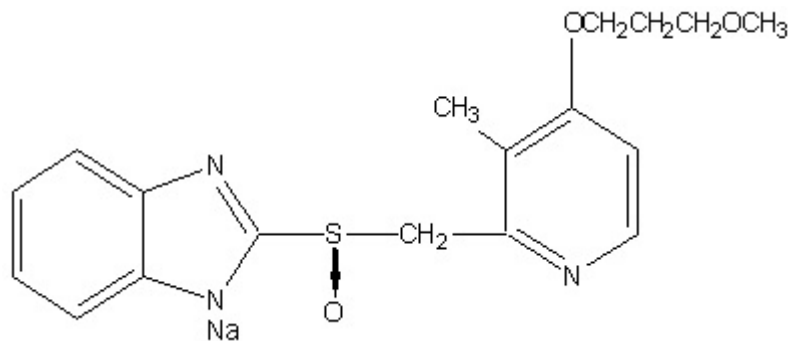
53. In the 1980s, anticipating that the PPI market would become increasingly lucrative, Eisai undertook a research project, known internally and in this litigation as the “SHKA” project, to discover a compound that would have a strong ability to inhibit acid secretion and would allow for a fast recovery of acid production once treatment had stopped. The former criterion determines the efficacy of the product. The latter was important because long-lasting acid inhibition was feared to cause undesired side effects. Using omeprazole as a “control” compound and with the above goals in mind, Eisai scientists worked in teams synthesizing and testing many different compounds for their ability to inhibit acid secretion. A compound that combined acid inhibition comparably effective to omeprazole but with significantly faster recovery was expected to be a commercially valuable competitor to omeprazole. (DTX 87T at

ECL 120417, 120588; Murakami Dep. 9:24-10:4, 10:7-24, 12:17-22, 34:19-23, 34:25-35:114; Ueda Dep. 11:21-23, 54:3-57:10, 238:17-25, 239:2-239:3.)

54. Eisai synthesized and tested a number of compounds as part of the SHKA project. One such compound, referred to internally as SHKA 661, was synthesized in late September 1986. (DTX 1123, Response to RFA 98; DTX 50T at ECL 140766; Fujisaki Dep. 226:13-17).

55. Also as part of its SHKA project, Eisai synthesized rabeprazole, known internally as SHKA 692, in October 1986. (DTX 50T at ECL 140766.)

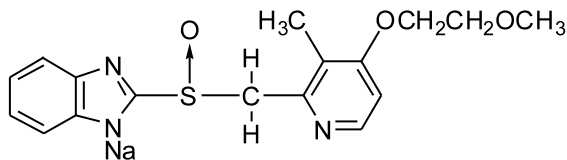
56. Rabeprazole has the following chemical structure:



(Statement of Agreed Facts ¶ 38.) Thus, rabeprazole includes a methyl substituent on the 3-position of the pyridine ring and a methoxypropoxy substituent on the 4-position of the pyridine ring, and it is unsubstituted at the 5-position of the pyridine ring. (Id. ¶ 41.)

57. Rabeprazole, the compound claimed in the '552 patent at issue in this case, functions as a "proton pump inhibitor," because it suppresses gastric-acid production by inhibiting the action of the H<sup>+</sup>K<sup>+</sup>ATPase enzyme. (Id. ¶ 28).

58. The compound referred to as SHKA 661 has the following chemical structure:





It is often referred to by the parties to this litigation as the “ethyl homolog” of rabeprazole, because its chemical structure is identical to that of rabeprazole save that it includes one fewer methylene (CH<sub>2</sub>) unit at the 4-position of the pyridine ring than rabeprazole – in other words, it bears an “ethyl” group where rabeprazole bears a propoxy group. (LaVoie Aff. ¶ 31, 39; Smith Aff. ¶ 26; Cooperman Aff. ¶ 23; see Murakami Dep. 252:21-253:16, 253:18.)

59. Defendants claim that Eisai “tweaked” SHKA 661 to produce rabeprazole. (D. Proposed Findings of Fact and Conclusions of Law (“D. Proposed Findings and Conclusions”) ¶ 66.) This is not accurate. Dr. Shigeru Souda, the leader of the SHKA research team, credibly testified that despite the similarity of chemical structure, rabeprazole cannot easily be, and was not, synthesized simply by “inserting” an additional methylene unit into an existing molecule of SHKA 661. (3/14/07 Tr. 975:6-979:10.) Moreover, despite a general principle that compounds similar in structure may be expected to have similar functionality, Eisai’s research demonstrated that the behavior of chemicals sharing the Brändström core structure was difficult to predict. (DTX 87T at ECL 120499; 3/14/07 Tr. 982:17-988:3.) Thus, there was no particular incentive for Eisai to “tweak” SHKA to produce rabeprazole, which ultimately was created as SHKA 692.<sup>7</sup>

60. While Eisai’s research showed SHKA 661 and SHKA 692 to exhibit similar proton pump-inhibition efficacy, (Forte Aff. ¶ 7), it indicated SHKA 692 to be superior in terms of acid-production recovery. (DTX 87T at ECL 120499; 3/14/07 Tr. 987:8-988:3.)

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<sup>7</sup> Indeed, referring to SHKA 661 as the “ethyl homolog” of rabeprazole, while chemically accurate, carries a potentially misleading implication. There is no evidence that Eisai research scientists referred to the compound by this name, or thought of SHKA 661 and SHKA 692 (rabeprazole) primarily in relation to each other.

61. Eisai filed the first Japanese priority application claiming rabeprazole in November 1986. (PTX 4T at B.) In February 1987, Eisai researchers formally proposed, in a document called a “Theme Registration,” that Eisai management invest in developing rabeprazole sodium (SHKA 692) as their commercial product. (PTX 55T.) Rabeprazole was a potentially desirable commercial product because it fit the criteria established by Eisai in undertaking the SHKA project better than any other compound tested, offering effectiveness comparable to omeprazole with significantly improved recoverability. (DTX 87T at ECL 120499; 3/14/07 Tr. 982:17-988:3.)

## **VI. Prosecution of the ’552 Patent and the Later-Filed Co-pending Application**

### **A. The Filing of the ’552 Application**

62. Eisai filed the application for the ’552 patent in the United States on November 10, 1987.<sup>8</sup> The ’552 application issued as a patent on September 3, 1991. (PTX 1.)

63. Eisai’s in-house patent attorney in Japan, Mitsuo Taniguchi, retained U.S. attorney Arthur Crawford to file and prosecute the ’552 patent application with the PTO. Taniguchi was involved in drafting the ’552 application and was the chief Eisai contact for its prosecution. (Statement of Agreed Facts ¶¶ 65, 71, 73-76.)

64. The ’552 application claimed priority to three Japanese patent applications, which had been filed previously in Japan. The earliest of these Japanese patent applications was filed

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<sup>8</sup> The ’552 patent issued on September 3, 1991, from United States Patent Application Serial No. 07/462,328 (“the ’328 application”), filed December 28, 1989. The ’328 application was a continuation of Application Serial No. 07/119,386, filed on November 10, 1987. These applications are referred to in this litigation collectively as the “’552 patent application” or the “’552 application.” The ’552 patent application claimed the benefit of the filing dates of certain priority applications previously filed in Japan beginning on November 13, 1986. (Statement of Agreed Facts ¶ 44).

on November 13, 1986, slightly less than twelve months earlier. (PTX 1.)

65. Original claim 1 of the '552 application claimed a genus of numerous different compounds. (PTX 2, '552 application, at DRLRAB 230-34.) Claim 1 of the '552 application is the same in all pertinent respects as the Japanese priority application. (PTX 4T at 1-5.)

66. The compounds originally claimed in the '552 application had a basic skeletal or core structure that sometimes included a benzimidazole ring on the left-hand side, a methylsulfinyl bridge in the middle, and a pyridine ring on the right. The claims also included different possible substituents at different places of the benzimidazole and pyridine rings, denoted in the original claims by the designations R1, R2, J, K, m, and Z. (PTX 2 at DRLRAB 230-234.) Numerous compounds featured the basic PPI chemical structure of benzimidazole ring/methylsulfinyl bridge/pyridine ring.

67. The '552 application as filed had 17 claims, 16 of which depended from Claim 1 or from other claims which in turn depended from Claim 1. Claim 7 of the '552 application recited: "The compound of claim 6, in which R1 and R2 are both hydrogen, J is methyl, m is 3 and R9 is methyl." Dependent claim 6 in turn recited: "The compound of claim 1, in which X is nitrogen, K is hydrogen, n is one, and Z is -OR9, R1 and R2 are both hydrogen or R1 is 5-lower alkyl, 5-halogenated lower alkyl or 5-lower alkoxy and R2 is hydrogen, J is hydrogen or methyl and m is 3 to 10, and R9 is lower alkyl." (PTX 2 at DRLRAB 235.) Dependent Claim 7 thus covers rabeprazole sodium. Rabeprazole is specifically shown in the '552 patent specification as Compound 19 and Example 33. (*Id.* at DRLRAB 70, 144.)

68. The '552 application provides significant disclosures regarding prior art. It identifies the Junggren patents covering omeprazole, U.S. Patent Nos. 4,337,257, 4,255,431 and 4,508,905.

Further, the '552 application identifies an additional compound, referred to in this litigation as "Example 27 of Junggren," from the working examples of the Junggren patent. (PTX 2 at DRLRAB 55; see PTX 7, Junggren '431 Patent, Table 2).<sup>9</sup> The '552 application specification also cites Great Britain patent application GB 2,134,523A ("GB '523") and identifies Example 157 of that application. (PTX 2 at DRLRAB 55.)

69. Along with the filing of the '552 application, Eisai also submitted an Information Disclosure Statement disclosing the Junggren patents and European Patent No. 167,943 to Beecham ("Beecham"). (PTX 2 at DRLRAB 242-43; see also DTX 1005.)

70. The '552 application sets forth in detail a discussion of three pharmacological experiments: an *in vitro* test of the ability of over 20 different compounds, including omeprazole, to inhibit the activity of the specified enzyme, and *in vivo* tests comparing rabeprazole with omeprazole in dogs. (PTX 2 at DRLRAB 65-76.)

71. Claim 1 of the patent included a "proviso" limiting the scope of the claim. (PTX 2, at DRLRAB 233-234.) The same proviso language appeared in the November 1986 original Japanese priority application. (Statement of Agreed Facts ¶ 47.) Use of a "proviso" is common in patent applications claiming a genus of chemical compounds, the aim being to prevent the claims from reading on prior art. (3/5/07 Tr. 108:3-13, 110:4-8.) The effect of the proviso in this case was to exclude the ethyl homolog from the claims of the '552 patent application.

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<sup>9</sup> The scientific name of this compound is "2-(4-methoxyethoxypyridine-2-yl)-methylsulfinyl-5-methyl-1H-benzimidazole." (PTX 7.)

**B. The Filing of the '013 Patent Application**

72. On June 16, 1988, some seven months after the '552 application was filed, Eisai filed a separate patent application, referred to in this litigation as the "'013 application."<sup>10</sup> (Statement of Agreed Facts ¶ 56.)

73. Crawford filed the '013 application on behalf of Eisai. (3/5/07 Tr. 74:13-25.) While he was substantively involved with the preparation for filing of the '552 application, he had "no substantive involvement" with preparing the '013 application. (3/6/07 Tr. 296:19-298:23.)

74. As with the '552 application, Taniguchi was involved in drafting the '013 application and served as Eisai's chief point-person in its U.S. prosecution during the relevant time. (Statement of Agreed Facts ¶¶ 77, 78; DTX 1142, Response to RFA at 338.)

75. The same PTO examiner did not review the '552 and '013 patent applications, whose prosecutions overlapped by about three years. (See DTX 103 at DRLRAB 2355; DTX 101 at DRLRAB 480.) Both patent applications were, however, assigned to the same "art unit" of the PTO, consisting of approximately 10 to 20 examiners. (3/6/07 Tr. 322:13-16, 342:24-343:5; 3/13/07 Tr. 779:3-9, 802:5-803:8.)

76. Original claim 1 of the '013 application is a genus encompassing a large number of compounds having alkoxyethoxy at the 4-position of the pyridine ring. The '013 application included 23 additional claims, all of which were dependent on Claim 1. Dependent Claim 8 of the '013 application recites a compound which is the ethyl homolog of rabeprazole. (PTX 16at

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<sup>10</sup> U.S. Patent Application Serial No. 07/207,626 was filed on June 16, 1988. Application Serial No. 07/207,626 was the first in a series of patent applications that ultimately issued as U.S. Patent 5,708,013 ("the '013 patent"). These applications are collectively referred to as the '013 patent application" or "the '013 application". (Statement of Agreed Facts ¶ 56).

DRLRAB 2342-43).

77. The '013 application shared certain similarities with the '552 application. The two named the same 14 inventors. (See DTX 101 at DRLRAB 000238-41; DTX 103 at DRLRAB 2351-53.) Both were directed to compounds for treating ulcers – in fact, one bore the title, “Pyridine Derivatives Having Anti-Ulcerative Activity,” while the other was entitled, “Pyridine Derivative and Therapeutic Agent for Ulcer Comprising the Same.” (See DTX 101 at DRLRAB 51; DTX 103 at DRLRAB 2280.) Both described the same background art and claimed to have identified compounds, based on the same basic core structure, that had superior potency and recoverability as compared to omeprazole. (DTX 101 at DRLRAB 54-55, 71-72, 230; DTX 103 at DRLRAB 2281-82, 2284-85, 2312, 2342.)

78. The '013 and '552 applications also both contained *in vitro* testing data for some compounds demonstrating acid-inhibition property. (DTX 101 at DRLRAB 66-71; DTX 103 at DRLRAB 2310-11.) The '013 application describes *in vitro* testing of 13 compounds to determine their ability to inhibit acid-causing PPI activity. (PTX 16 at DRLRAB 2308-12.) The compounds with the greatest reported *in vitro* potency are, in descending order, Compounds 3, 7 and 11. (*Id.* at DRLRAB 2310-11.) None of these compounds is rabeprazole or the ethyl homolog of rabeprazole.

79. Eisai has presented testimony, which this Court finds credible, to explain why it pursued a separate patent claiming, *inter alia*, the ethyl homolog, rather than pursuing claims to the ethyl homolog and to rabeprazole via one application. It is common ground to both parties that the rabeprazole patent was important to Eisai, because Eisai considered rabeprazole a potentially lucrative commercial drug. According to Taniguchi, Eisai believed that both

rabeprazole and the ethyl homolog were patentable,<sup>11</sup> but feared that the ethyl homolog might invite “later attack” by the owner of Junggren, because “the Junggren patent discloses methoxyethoxy,” a substituent of the ethyl homolog. (3/08/07 Tr. 597:1-608:5.) Accordingly, the ’552 patent application was drafted to cover rabeprazole and other compounds but to exclude the ethyl homolog, which Eisai believed could be patented at a later date, in order to expedite consideration of the more important compound. (3/08/07 Tr. 597:1-608:5.)

### **C. The First Office Action in the ’552 Application and Eisai’s Response**

80. On September 21, 1988, Examiner Fan, to whom the ’552 application had been assigned, issued an office action rejecting all of the then-pending claims of the ’552 patent application, including the claims covering rabeprazole, as obvious over prior art Junggren and GB ’523. (DTX 101 at DRLRAB 292-93; Smith Aff. ¶ 107.) She specifically cited and diagrammed Example 27 of Junggren – a compound Eisai had specifically disclosed in its patent application – which bears a methoxyethoxy substituent at the 4-position of its pyridine ring. (Id.) She also specifically noted Examples 156 and 157 of GB ’523, which compounds Eisai had also pointed out in the ’552 patent specification. (PTX 2 at DRLRAB 288-95.)

81. Examiner Fan wrote that “Junggren . . . and [GB ’523] generically teach[] R4 being methoxyethoxy or ethoxyethoxy and Junggren [Example 27] specifically teaches . . . the following compound [Example 27 diagram] as such, the art compounds are homologs of the claimed compounds rendering the claimed compounds unpatentable. The proviso statement only excludes 102b rejection not 103 rejection.” (DTX 101 at 292-93.) She thus indicated her belief

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<sup>11</sup> The patentability of the ethyl homolog was credibly supported by plaintiffs’ expert Hopfinger. (Hopfinger Aff. 79-87.)

that compounds within the Junggren and GB '523 prior art she was citing were homologous to the claimed compounds, rendering the claimed compounds unpatentable as obvious under 35 U.S.C. § 103.

82. On March 21, 1989, Crawford responded on behalf of Eisai to Examiner Fan's September 1988 office action. In one section of the response, Eisai amended its claims to narrow the scope of the '552 application. (DTX 101 at DRLRAB 427.) In the next section, under the heading, "Response to Rejections Based Upon Prior Art," Eisai stated:

In contrast to applicants' claims, GB 2134523A and U.S. '431 disclose only compounds where the methoxyethoxy group is attached to the 4-position of the pyridine ring, thus novelty is established. Specific compounds disclosed in the published British application and issued U.S. patents are substituted at both the 3- and 5-position by methyl groups, as in the GB patent, or unsubstituted in both the 3- and 5-positions. Applicants' claims allow for the possibility of unsubstitution or a lower alkyl at the 3-position with no substitution at the 5-position; preferably the 3-position (J in the generic formula) is methyl.

(DTX 101 at DRLRAB 429.) The next paragraph, in the same section, begins, "Having established essential novelty for the claims under consideration, attention will now be given to the unexpected anti-ulcer activity of such compounds." (Id.)

83. It is clear from their context that the statements attempting to distinguish the prior art compounds' 4-position methoxyethoxy and symmetrically substituted pyridine rings from structural aspects of Eisai's claimed compounds constituted an argument for novelty. The argument was inapposite, as Fan had not rejected the claims covering rabeprazole for lack of novelty.

84. In the remaining portion of the March 21, 1989, response, Eisai argued that the claimed compounds were nonobvious because they demonstrated unexpectedly superior acid-



inhibition efficacy as compared to omeprazole. (DTX 101 at DRLRAB 429-33.) In particular, the response referred to the comparative data between rabeprazole and omeprazole shown in Table 1 of the specification of the '552 patent application (id. at DRLRAB 66-71), and stressed that the inhibitory effect of rabeprazole was approximately 10 times greater than that of omeprazole, (id. at DRLRAB 431).

85. Eisai's response specifically indicated certain claimed compounds as exhibiting "excellent inhibitory action as compared with Omeprazole," including one – compound 3 in Table 1 of the '552 application specification – that contained a trifluoromethyl (-CF<sub>3</sub>) substituent on the benzimidazole ring . (Id. at DRLRAB 66, 431.)

86. In its response of March 21, 1989, Eisai did not challenge Fan's *prima facie* obviousness rejection, but instead sought to show that the claimed compounds were patentable for their unexpected properties – specifically, properties of greater inhibition of acid secretion and faster recovery of acid secretion as compared to omeprazole. Eisai argued that the examiner should accept its comparison of rabeprazole to omeprazole, even though Example 27 of Junggren was the structurally closest prior art, because omeprazole was considered the most promising compound in development and had, as Junggren itself showed, greater acid-inhibition activity than Example 27. Eisai was thus asking for an exception to the general rule that a compound should be compared to the structurally closest prior art compound, citing "In re Fouche, 169 USPQ 429 (CCPA 1969) [*sic*]." (PTX 2 at DRLRAB 430.)

**D. Eisai's Internal March 23-24, 1989, Communications Concerning Data Disclosures at a Pharmaceutical Trade Conference**

87. On March 23, 1989, Eisai inventor Shuhei Miyazawa faxed Taniguchi a note along with copies of various slides of data he proposed to share at a meeting of the Pharmaceutical

Society of Japan, asking whether “there are any sections which may present an obstacle to obtaining a patent, particularly, a U.S. patent.” He noted that certain included compounds “fall within the scope of the Hässle patent,” among them the ethyl homolog; at trial he testified to believing that Eisai had “discovered the superior properties” of these compounds. (DTX 53AT at ECL 141318, 141322; 3/7/07 Tr. 529:16-530:7.) His note stated that a certain slide entry about the ethyl homolog “consists of data on effect and recoverability that is no different from the developed product” (DTX 53AT at ECL 141318); at trial he testified that, in fact, the slide he mentioned – as evident from its face – did not reflect recoverability data at all, and that “what I meant is that between the two [rabeprazole and the ethyl homolog] there should have been a difference in terms of recoverability, but that is not shown here” (*id.*; 3/7/07 Tr. 526:12-527:5). He also testified, reviewing these slides that he had created, that the slides he had faxed to Taniguchi showed the ethyl homolog to be equivalent to rabeprazole in terms of acid inhibition efficacy, but that the slides contained no comparison between the two in terms of acid recovery rate. (3/7/07 Tr. 529:1-10; DTX 53AT at ECL 141318-28.) He also testified that his expressed concerns about patentability had to do with the possibility that competitors, including Hässle, would learn of Eisai’s discoveries and “somehow attack our patent.” (3/7/07 Tr. 530:2-7.)

88. Later that day, Taniguchi advised Miyazawa to remove the data regarding the ethyl homolog to “be safer,” in his faxed response crossing out mention of the ethyl homolog and its data from the information Miyazawa had sent him. (DTX 53AT at ECL 141329, 141332). At trial Taniguchi testified that he understood Miyawaza’s reference to the “Hässle patent” at the time to mean the Junggren patents discussed in this litigation, and that he understood Miyazawa’s reference to “the developed product” to mean rabeprazole. (3/8/07 Tr. 630:17-

631:3.) He further testified that he believed it would be “safer” to delete certain data about compounds covered by other entities’ patents from a conference presentation that representatives of such entities were likely to attend, for fear of provoking those entities to take some form of adversarial, proprietary action. (Id. at 635:15-637:2.) He testified that this concern was his sole motivation for advising Miyazawa to delete certain data, stating, “I had absolute no thoughts that related to the . . . U.S. patent office.” (Id. at 637:7-8.) In light of explicit references to the PTO in other parts of the Miyazawa-Taniguchi exchange, this testimony is not credible.

89. Miyazawa wrote Taniguchi again the following day, seeking advice on whether to include certain additional data in his presentation to the Pharmaceutical Society. The data consisted of acid inhibition and recovery results for a list of compounds including rabeprazole (but not including the ethyl homolog). (DTX 53AT at ECL 141339-40; 3/7/07 Tr. 523:1-524-22.) Miyazawa’s fax specially indicated for Taniguchi’s attention three compounds; these compounds were symmetrically substituted at the pyridine ring with a methoxypropoxy or methoxybutoxy at the 4-position. (DTX 53AT at ECL 141339-40.) At trial, Miyazawa reviewed the data that he had faxed Taniguchi and testified that, considering the depicted results for acid inhibition and recovery overall, rabeprazole appeared to him to be the superior PPI compound on the list. (3/7/07 Tr. Tr. 523:1-524-22.)

90. Taniguchi wrote back to Miyazawa, advising that “it would be safer if you could omit” the three specially indicated, symmetrically substituted compounds. (DTX 53AT at ECL 141340-41.) His note explained that “there is a dialogue underway with the USPTO examiner at present,” in which the Junggren patent, containing symmetrically substituted compounds, was being cited by the PTO. He wrote that Eisai might have to limit its claims to an asymmetrically

substituted compound and that, “[t]herefore . . . it would be desirable if there was data showing that [an asymmetrically substituted compound] is superior in comparison to those in which both [the 3- and 5-positions] are either hydrogen or methyl groups.” (DTX 53AT, ECL 141341-42.) At trial, Taniguchi testified that at the point when he wrote this note, he was concerned about the ’552 patent application and anticipated that it would have to be narrowed to the asymmetrical rabeprazole, but that his primary reason for advising Miyazawa to delete mention of the three compounds remained his concern about competitors’ possible reaction. (3/12/07 Tr. 649:18-650:10.)

**E. The First Office Action in the ’013 Application on April 21, 1989**

91. On April 21, 1989, almost a year after Eisai’s filing of the ’013 application, the examiner issued his first office action rejecting the claims. (PTX 16 at DRLRAB 2469-73.) Claims 1-8 (8 claiming the ethyl homolog), 10-12, 14-16, 18, 23 and 24 of the ’013 application were rejected as a group as anticipated by Junggren, while claims 9, 13 and 17 were rejected as obvious over Junggren in view of U.S. Patent No. 4,555,518 and in view of Byk Gulden ’646. Like Examiner Fan, the ’013 application examiner specifically cited Compound 27 of Junggren in support of his rejection. (*Id.* at DRLRAB 2469-73.)

92. The ethyl homolog was covered by the generic disclosure of the Junggren patent, which patent application Eisai had disclosed to the ’552 patent examiner as prior art. However, Junggren does not specifically disclose or claim the ethyl homolog. (*See* DTX 101 at DRLRAB 244-286; DTX 1139, Response to RFA 24.) Defendants conclusorily allude to the ethyl homolog as a “Junggren compound[.]” (D. Post-Trial Br. at 16), to suggest that the ethyl homolog was a prior art compound to rabeprazole, but they show no specific disclosure or even preference

in Junggren pointing to the ethyl homolog. Indeed the evidence, including expert testimony offered by both plaintiffs and defendants, establishes that the ethyl homolog was not actually a prior art compound to rabeprazole as within Junggren. (3/12/07 Tr. 739:17-19; Hopfinger Aff. ¶¶ 76-87.)

93. The three claims rejected in part on the basis of Byk Gulden did not include the ethyl homolog. (Smith Dep. 250:2-9). These claims specifically required and were limited to a trifluoromethyl substitution on the benzimidazole ring as “R1.” (PTX 16 at DRLRAB 2344-45; Smith Dep. 250:19-23). The examiner of the ’013 application explained the rejection of these three claims: “The difference between the Junggren reference [and] applicant’s claimed compounds is the trifluoromethyl group on the benzene ring of benzimidazole. Both [Byk Gulden] and [U.S. Patent No. 4,555,518] teach trifluoromethyl [*sic*] substitution of the benzene ring in similar compounds useful as gastric secretion inhibitors. Since these compounds are all useful as gastric inhibitors and are all closely related in structure, one of ordinary skill would be motivated to combine the reference to produce applicant’s compounds.” (PTX 16 at DRLRAB 2473). The ’013 application examiner did not cite any specific pages or lines of Byk Gulden.

#### **F. The Second Office Action in the ’552 Application on July 14, 1989**

94. On July 14, 1989, Examiner Fan issued a second office action in the ’552 application, rejecting the claims based on the same prior art already of record. She found “unpersuasive” the arguments in Eisai’s response of March 21, 1989. (PTX 2 at DRLRAB 440-42.)

95. Examiner Fan stated that “the statement at middle part of page 9” – the attempted asymmetrical substitution distinction – “of applicants’ remark is not understood,” because “[t]he

claimed compounds encompass both 3.5 positions substituted by lower alkyl.” (Id. at DRLRAB 441.) Handwritten question marks appearing in the margin of the PTO-produced copy of Eisai’s March 21, 1989, response, alongside the distinction assertion, accord with Fan’s comment that she did not understand Eisai’s assertion. (Id. at DRLRAB 429.)

96. Examiner Fan also refused to accept Eisai’s attempt to show unexpected properties by comparing rabeprazole to omeprazole rather than to a structurally closer compound. She stated that, “[i]n the unpredictable medicinal field, one can not assume a compound’s pharmaceutical activity. Actual comparison has to be made in order to establish unexpected property.” (Id. at DRLRAB 441).

97. Accordingly, as of July 14, 1989, the examiner in the ’552 application had made clear that the obviousness rejection over Junggren was maintained, and that Eisai would need to provide data showing unexpected properties from an actual comparison of the claimed compounds to the closest prior art to overcome that obviousness rejection.

**G. The August 3, 1989, Meeting between Crawford and Examiner Fan and the Confirming July 17, 1990, Office Action in the ’552 Application**

98. On August 3, 1989, a few weeks after entry of the July 14, 1989, office action, Crawford met with Examiner Fan on behalf of Eisai regarding the ’552 application. In her written “Examiner Interview Summary Record” regarding the meeting with Crawford, Fan wrote:

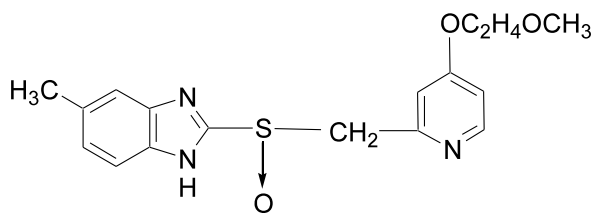
Applicants may be willing to limit the invention to claim 21, as such compounds with 4-position pyridyl substituents being ethoxyethoxy and methoxyethoxy should be compared. If applicants are willing to limit the invention to the cpd at p. 16 of March 31, 1989 remark [i.e., rabeprazole], then only methoxyethoxy cpd need to be compared.

(PTX 2 at DRLRAB 449.) It is evident, from the context of the documented record of the '552 application to that date, that the “methoxyethoxy cpd” to which Fan referred was the compound on which the outstanding initial rejection had been based, Example 27 of Junggren. (See id. at DRLRAB 292-93.) Fairly read in the context of the ongoing prosecution, Fan’s written record reflects an agreement achieved during her meeting with Crawford that, if Eisai limited the '552 application in certain ways, it would accordingly be required to compare results only with certain prior art; if Eisai limited its claims only to rabeprazole, then it would be required to compare its purported invention only to Junggren 27, the closest prior art to rabeprazole, to demonstrate unexpected results.

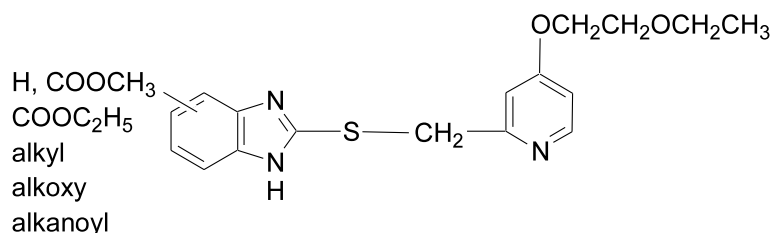
99. On December 28, 1989, Eisai filed a “File Wrapper Continuation Application” (“FWC application”), to avoid expiration of the claims. (DTX 101 at DRLRAB 52.)

100. On July 17, 1990, Examiner Fan re-issued the July 14, 1989, office action. (PTX 2 at DRLRAB 453-57.) Paragraphs 1-4 of the office action are virtually identical to the July 14, 1989, office action (other than specifying a date in paragraph 1). In a new paragraph, Fan wrote:

The closest prior art compounds should be compared with the claimed compounds . . . . In the instant case, art compound 27 of [Junggren] ‘431



. . . and the compounds of EP 74341 p. 5, lines 20-25 such as



should all be compared.

(*Id.* at DRLRAB 455.) This action embodied the agreement made at the meeting between Crawford and Fan.

#### **H. Eisai's October 20, 1989, Response in the '013 Application**

101. On October 20, 1989, Crawford submitted on behalf of Eisai a Response and Amendment to the initial '013 application rejection. After describing certain amendments that were being made, the response stated:

The amendments made to the main claim above now specify that R3 is methyl and R4 is hydrogen, a structure not contemplated by [Junggren] which contains identical substituents in the 3- and 5-positions, primarily either hydrogen or lower alkyl. By contrast, in the claims of the present application, the 5-position of the pyridine ring is always occupied by hydrogen (that is, it is unsubstituted), while the 3-position contains methyl.

(DTX 103 at DRLRAB 2504-07.) The statement resembles Eisai's assertion of an asymmetrical substitution distinction in response to the PTO's first rejection of its '552 application.

102. Eisai further directed the '013 application examiner to consider data it had previously submitted comparing the "gastric inhibitory activity" of the ethyl homolog and "the other [claimed] compounds" with "the activity of omeprazole" – even though Example 27 Junggren was structurally closer to the '013 application compounds – because omeprazole was "the best (apparently) compound of this particular class." (*Id.* at DRLRAB 2508.)



103. Along with its response, Eisai also disclosed to the '013 application examiner a reference that had been cited in the September 1988 rejection in the '552 prosecution. (DTX 103 at DRLRAB 2509-10.)

104. Eisai did not discuss Byk Gulden at all in the October 20, 1989, amendment and response in the '013 application. As is clear from the response, Eisai was seeking to overcome the rejection as based on Junggren. (Id. at DRLRAB 2507-09.)

**I. The Second Office Action in the '013 Application on December 6, 1989**

105. On December 6, 1989, the '013 application examiner issued a second Office Action rejecting all the claims “as anticipated by or, in the alternative, under 35 U.S.C. [§] 103 as obvious over Junggren . . . in view of [Byk Gulden],” and “as anticipated by or, in the alternative, under 35 U.S.C. [§] 103 as obvious over [a] Carlsson [patent] . . . in view of [Byk Gulden].” (DTX 103 at DRLRAB 2631-32.)

106. Disagreeing with Eisai’s October 1989 assertion that Junggren did not “contemplate[.]” asymmetrically substituted compounds, the examiner stated:

Junggren et al is not committed just to the symmetrical substituents. The generic formula discloses instant compounds by teaching asymmetrical substituents at the R3 and R5 positions. In column 9, examples 1-5, 16, 18 and 22 all teach asymmetrical substituents at the R3 and R5 positions. [Byk Gulden] discloses compounds which teach methoxyethoxy at the 4-position and methyl at the 3-position. See page 20, lines 1-2; page 21, lines 29-30; page 22, lines 8-9; and page 23, lines 36-37. One of ordinary skill in the art would be motivated to combine these references to produce the applicants’ claimed compound.

(Id. at DRLRAB 2631.)

**J. The June 6, 1990, Response and the August 9, 1990, Final Office Action in the '013 Application**

107. Eisai's June 6, 1990, response in the '013 application repeated its arguments that the symmetrical substitution pattern of the '013 application claims imparted distinctiveness. (PTX 16 at DRLRAB 2647.)

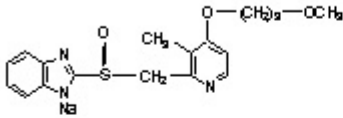
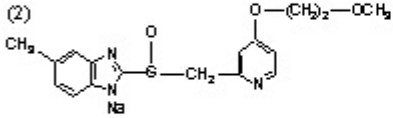
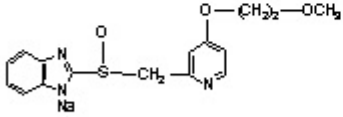
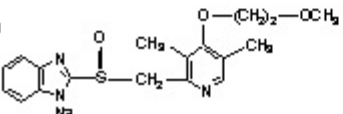
108. The '013 application examiner's August 9, 1990, final office action rejected these arguments over the same prior art and, expressly, for essentially the same reasons stated in the December 6, 1989, office action. (*Id.* at DRLRAB 2649-52.)

109. After the August 9, 1990, office action, nothing of substance happened in the '013 application for several years. Eisai filed several FWC applications, resulting in the examiner re-issuing the existing rejections.

**K. The January 11, 1991, Amendment and Fujisaki Declaration in the '552 Application**

110. On January 11, 1991, Crawford, as he had previously discussed with Examiner Fan, filed an amendment in the '552 application limiting the claims to rabeprazole. (PTX 2 at DRLRAB 463-67.)

111. In accordance with the August 3, 1989, meeting and the July 17, 1990, office action, Eisai submitted comparative activity data for a number of compounds that Taniguchi helped select. (3/12/07 Tr. 688:13-696:23.) The data were presented in the form of a "Rule 132 Declaration," signed by Hideaki Fujisaki ("the Fujisaki Declaration"). (PTX 2 at DRLRAB 466, DRLRAB 468-71.) The Fujisaki Declaration presented *in vitro* H<sup>+</sup> K<sup>+</sup>ATPase-inhibition data for rabeprazole (Compound (1)), the sodium salt of Example 27 of Junggren (Compound (2)), and two other compounds (Compounds (3) and (4)), via a chart:

<u>Compound</u>	<u>% Inhibiting activity 10<sup>-5</sup>(M)</u>	<u>IC50 (M)</u>
(1) 	95.6	1.7 x 10 <sup>-6</sup>
(2) 	30.8	>10 <sup>-6</sup>
(3) 	17.8	>10 <sup>-6</sup>
(4) 	27.3	>10 <sup>-6</sup>

(DTX 101 at DRLRAB 470). The presented data show rabeprazole to have comparatively superior inhibition activity. The Fujisaki Declaration provided Fan with precisely the comparison she had been seeking, between rabeprazole and prior art compound Example 27 of Junggren. (3/12/07 Tr. 734:8-19, 743:14-18.)

112. In the accompanying response, Eisai described the Fujisaki Declaration as “presenting comparative data between the compound of the invention having a methoxy-propoxy at the 4' position of the pyridine ring.” It claimed that rabeprazole “exhibits surprisingly unexpected inhibitory effects . . . in comparison with closely related compounds of the type referred to by the examiner” in previous office actions. The response referred to Fan’s mention of Junggren Example 27 in the July 17, 1990, office action, stating that “applicants have indeed compared the closest sulphonyl [sic] compound ethoxy methoxy with the claimed compound.”

(DTX 101 at DRLRAB 466).

113. On November 15, 1989, over one year prior to Eisai's submission of the Fujisaki Declaration, Eisai inventor Souda had sent Taniguchi a list of compounds and their inhibition activity data. The list included rabeprazole, the sodium salt of compound 27 of Junggren, compounds (3) and (4) of the Fujisaki Declaration, and the ethyl homolog; the data listed show the ethyl homolog to be more potent than Junggren 27 and compounds 3 and 4. (DTX 177T.)

**L. The April 3, 1991, Notice of Allowability in the '552 Application Based on Unexpected Properties Over the Closest Prior Art**

114. On April 3, 1991, Examiner Fan issued a Notice of Allowability of the '552 application claims. (PTX 2, '552 application, DRLRAB 472.) Examiner Fan stated in the Notice of Allowability that it was being issued "responsive to amdt of 1/11/91." (Id.) Thus, the file history shows that Examiner Fan approved the '552 application because the claims had been limited to rabeprazole and the examiner was given comparative data demonstrating unexpected results with respect to Example 27 of Junggren, just as she had requested in the August 3, 1989, interview and July 17, 1990, office action.

115. The '552 patent was formally granted on September 3, 1991. (PTX 1.)

**M. Continued Prosecution of the '013 Application Years After the Rabeprazole Patent Issued**

116. As discussed above, Eisai filed several FWC continuation applications in the '013 application, resulting in the examiner re-issuing the then-existing rejections.

117. On June 7, 1996, Eisai filed an amendment limiting the claims to compounds having, among other things, a butoxy-ethoxy substituent at the 4-position of the pyridine ring. (PTX 16 at DRLRAB 2747-53.) The pending '013 claims, therefore, no longer covered

compounds having a methoxyethoxy substituent at the 4-position of the pyridine ring, such as the ethyl homolog. On this basis, Eisai simply argued that “the prior art cited and applied in the outstanding Official Action is not pertinent to this particular group of compounds as now defined by applicants’ claims.” (Id. at DRLRAB 2753.)

118. With the claims no longer covering compounds having a methoxyethoxy substituent, on August 30, 1996, the ’013 application examiner withdrew the rejections involving the methoxyethoxy compounds of Byk Gulden, stating:

The rejection of old claims 6-18 and 23-25 (now 26-34) under 35 U.S.C. 103 as being unpatentable over Junggren et al. and [Byk Gulden] has been overcome.

(Id. at DRLRAB 2754-59.)

119. After withdrawing the rejection based on the methoxyethoxy compounds, the Examiner in the June 1996 office action entered a new rejection, citing, for the first time in the ’013 application prosecution, the disclosure of “C1-C4-alkoxy-C1-C4-alkoxy” in Byk Gulden. (Id. at DRLRAB 2756).

120. Eisai appealed the examiner’s reliance on this disclosure in Byk Gulden by directly challenging the *prima facie* rejection on February 28, 1997, and arguing that it was legal error to cite the generic disclosure in support of a rejection. (Id. at DRLRAB 2760-71). In response, on July 15, 1997, the ’013 examiner agreed that the rejection based on the “C1-C4-alkoxy-C1-C4-alkoxy” generic disclosure of Byk Gulden was improper, issuing a Notice of Allowability stating that “the instant compounds are patentable over the art of record because of the butoxy-ethoxy group at the 4-position of the pyridine compound, which was not taught by the prior art.” (Id. at DRLRAB 2773).

121. The '013 patent was granted on January 13, 1998. (See PTX 15.)

122. During some three years' overlap in the pendency of the '552 and '013 prosecutions, Eisai did not disclose the existence of, or any occurrences in, the '013 prosecution to the examiner of the '552 application. (Statement of Agreed Facts ¶¶ 90-93.)

## CONCLUSIONS OF LAW

### I. Applicable Legal Standards

1. Applicants have a duty to prosecute patent applications in the PTO with candor, good faith, and honesty. Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed.Cir.1995); see also 37 C.F.R. § 1.56(a) (1987) (explaining that the duty extends to, among others, inventors, their attorneys and agents, and “every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor”). A breach of this duty by falsification, misrepresentation, or omission of material information before the PTO, if committed with an intent to deceive, constitutes inequitable conduct and may render even a valid patent unenforceable. Molins, 48 F.3d at 1178. One alleging inequitable conduct must prove the elements of materiality and intent each by clear and convincing evidence. Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 872, 876 (Fed. Cir. 1988) (*en banc*) (overruling language in prior cases to make clear that even gross negligence was not in itself sufficient to find inequitable conduct).

#### A. **Intent To Deceive**

2. Proving intent to deceive means more than proving that the applicant intended to do what he did in patent prosecution; “it means that the inventor intended to deceive or mislead the Examiner into granting the patent.” Therma-Tru Corp. v. Peachtree Doors Inc., 44 F.3d 988, 995

(Fed. Cir. 1995); Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1367 (Fed. Cir. 2003) (“inequitable conduct requires not intent to withhold, but rather intent to deceive”).

3. “Intent to deceive can not be inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent.” Atofina v. Great Lakes Chem. Corp., 441 F.3d 991, 1001-02 (Fed. Cir. 2006) (citing Herbert v. Lisle Corp., 99 F.3d 1109, 1116 (Fed. Cir. 1996)); Purdue Pharma L.P. v. Endo Pharm. Inc., 438 F.3d 1123, 1134 (Fed. Cir. 2006).

4. Where information withheld from the patent office is highly material, and the applicant knows or should have known of its materiality, courts may infer a deceptive intent. Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1257 (Fed. Cir. 1997). “[S]moking gun’ evidence is not required in order to establish intent to deceive.” Paragon Podiatry Lab., Inc. v. KLM Labs., Inc., 984 F.2d 1182, 1189 (Fed. Cir. 1993). Intent “must generally be inferred from the facts and circumstances surrounding the applicant’s overall conduct.” Id. at 1190. In the end, intent to deceive is a question of fact, to be decided by the factfinder based on all the evidence in the case. See Molins PLC, 48 F.3d at 1178; Halliburton Co. v. Schlumberger Technology Co., 925 F.2d 1435, 1439 (Fed. Cir. 1991).<sup>12</sup>

## **B. Materiality**

5. Information is material to the prosecution of a patent where “there is a substantial likelihood that a reasonable examiner would have considered the information important in

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<sup>12</sup> For this reason, the Court’s conclusions with respect to various actors’ intentions or other states of mind are best considered to be findings of fact rather than legal conclusions. Because they represent the Court’s ultimate, controlling conclusions, however, and for ease of understanding, they are presented in this more analytic portion of the opinion, rather than with the findings of historical fact set forth above.

deciding whether to allow the application to issue as a patent.” Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1575 (Fed. Cir. 1996); 37 C.F.R. § 1.56(a) (1987).

Information need not by itself be outcome-determinative to be considered material. Li Second Family Ltd. v. Toshiba Corp., 231 F.3d 1373, 1380 (Fed. Cir. 2000).<sup>13</sup>

6. Information that is merely “cumulative” of (or not more pertinent than) information already possessed by the Examiner cannot, as a matter of law, be material. Litton Sys., Inc. v. Honeywell, Inc., 87 F.3d 1559, 1570-71 (Fed. Cir. 1996), vacated on other grounds, 520 U.S. 1111 (1997).

7. “[A]ffirmative misrepresentations by the patentee, in contrast to misleading omissions, are more likely to be regarded as material.” Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1367 (Fed. Cir. 2003). While it is “axiomatic that close [questions] should be resolved [on the part of applicants] by disclosure,” GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1274 (Fed. Cir. 2001), when the disputed conduct amounts to an omission or withholding

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<sup>13</sup> Defendants occasionally attempt to apply a newer standard of materiality, specifically that information meets the threshold level of materiality if “[i]t refutes, or is inconsistent with, a position the applicant takes in . . . [a]sserting an argument of patentability.” 37 C.F.R. § 1.56(b)(2)(2002). However, with respect to patents prosecuted prior to the PTO’s 1992 amendment of its rules – as was the ’552 patent in this case – the Federal Circuit has applied the judicially-adopted standard of materiality set forth in the pre-1992 version of 37 C.F.R. § 1.56: whether there is a substantial likelihood that a reasonable examiner would consider the information important in deciding whether to allow the given application to issue as a patent. This Court stated this standard in its opinion resolving Eisai’s request for summary judgment of no inequitable conduct, and neither party has objected. See Eisai I, 472 F. Supp. 2d at 507, citing Dayco, 329 F.3d 1358, 1364 (Fed. Cir. 2003); cf. Purdue Pharma, 438 F.3d at 1129 (“Because all of the patent applications at issue . . . were pending on or filed after March 16, 1992, we look to the current version of Rule 56, rather than the pre-1992 version of the rule”). Accordingly, for purposes of resolving the issues litigated at trial, the pre-1992 standard cited in the text is the correct standard. In any event, this Court’s ultimate conclusion, finding no inequitable conduct based largely on the lack of deceptive intent, would not differ under the newer standard of materiality.



of information, “the level of materiality is not especially high.” Purdue Pharma, 438 F.3d at 1133.

### **C. Balancing**

8. Even if threshold materiality and intent are established, that does not in and of itself establish inequitable conduct. Instead, the Court must go farther and weigh the evidence of materiality and intent against all other circumstances to determine whether conduct so culpable as to justify unenforceability has indeed occurred. Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A. DE C.V., 464 F.3d 1339, 1346 (Fed. Cir. 2006); Baxter Int’l, Inc. v. McGaw, Inc., 149 F.3d 1321, 1327 (Fed. Cir. 1998).

9. The Federal Circuit has noted that inequitable conduct is a defense frequently raised, but not often proved, and has urged restraint in applying a defense that prevents enforcement of a valid patent. Preemption Devices, Inc. v. Minnesota Mining & Mfg. Co., 732 F.2d 903, 908 (Fed. Cir. 1984); Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1454 (Fed. Cir. 1984); Burlington Indus., Inc. v. Dayco Corp., 849 F.2d 1418, 1422 (Fed. Cir. 1988); see Kingsdown, 863 F.2d at 873 (*en banc*) (alleged act of inequitable conduct “did not result in the patenting of anything . . . in the prior art and thus took nothing from the public domain.”); Kemin, 464 F.3d at 1345-6 (even with threshold findings of materiality and intent, finding of no inequitable conduct affirmed when reference did not invalidate the patent and was therefore “not highly material and the showing of deceptive intent was not compelling.”).

## **II. Nondisclosures Relating to the Co-pending ’013 Patent Application**

### **A. Materiality**

10. Defendants argue that the mere fact of the ’013 application’s concurrent existence

was information that a reasonable examiner would have considered important to know in deciding whether to allow the '552 application to issue, because the examiner could have issued a “provisional obviousness-type double patenting rejection” to avoid bestowing duplicative rights on Eisai. (D. Proposed Findings and Conclusions ¶¶ 182, 226-235.) MPEP § 2001.06(b) during the relevant time required the disclosure of co-pending applications claiming patentably indistinct subject matter.<sup>14</sup> Defendants contend that, “because rabeprazole and the ethyl homolog are adjacent homologs, and share a similar known use, i.e. the treatment of peptic ulcers, the claims of the rabeprazole application are . . . patentably indistinct from the claims of the co-pending ethyl homolog application.” (*Id.* ¶ 234.)

11. However, it is less than clear that the '552 application would have been subject to a provisional double patenting rejection – or, as pertinent to the deceptive intent inquiry, that Eisai actors would have thought so – simply because the claims of the '013 application included a homolog of one of the compounds of the '552 application. Compounds are patentably indistinct when they are *prima facie* obvious variants of each other – “obvious,” that is, “from the subject matter of the claims in the [co-pending] patent [application], in light of the prior art.” *In re Longi*, 759 F.2d 887, 892-93 (Fed. Cir. 1985); *see In re Dillon*, 919 F.2d 688, 692, 696 (Fed. Cir.

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<sup>14</sup> The Manual of Patent Examining Procedures (“MPEP”), promulgated by the PTO, sets forth practices to be followed by patent applicants and PTO processes of which they should be aware, pursuant to the duty of candor. While the MPEP does not constitute binding law, it has received judicial notice as an official interpretation of patent law. *Litton Sys. v. Whirlpool Corp.*, 728 F.2d 1423, 1439 (Fed. Cir. 1984), overruled in part on other grounds by *Two Pesos, Inc. v. Taco Cabana, Inc.*, 505 U.S. 763 (1992). In an inequitable conduct dispute, moreover, the MPEP serves as a common articulation of patenting norms, indicating what information is appropriately considered material and reflecting on the intentions of an applicant who does not follow it. Thus, while a violation of standards set forth in the MPEP does not *ipso facto* constitute sufficient proof of inequitable conduct, courts appropriately take note of it as evidence of what a reasonable patent examiner would consider material.

1990) (*en banc*) (“[S]tructural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a *prima facie* case of obviousness . . . . Exactly what facts constitute[] a *prima facie* case varies from case to case.”). Defendants oversimplify this *prima facie* obviousness inquiry in stating that it “can be based on structural similarity alone.” (D. Proposed Findings and Conclusions ¶ 230.) By 1985, the Court of Appeals for the Federal Circuit had cautioned that “generalization should be avoided insofar as specific chemical structures are alleged to be *prima facie* obvious one from the other.” In re Grabiak, 769 F.2d 729, 731 (Fed. Cir. 1985). Homologs are not necessarily *prima facie* obvious with respect to one another. See Dillon, 919 F.2d at 696 (discussing *prima facie* obviousness where the prior art provides a motivation to make close relatives, including homologs, of art compounds). Defendants have failed to establish a factual, prior-art based path by which rabeprazole and its ethyl homolog would have been deemed by the PTO to be *prima facie* obvious over one another – and, thus, patentably indistinct – offering only conclusory or unpersuasive expert testimony to that end. (See D. Proposed Findings and Conclusions ¶¶ 229, 233, 234.)

12. Nor have defendants established the indistinctness of the two patent applications beyond the issue of *prima facie* obviousness as between two particular compounds respectively claimed in those applications. The ’013 application was not directed to a single compound, and it included many different compounds besides the ethyl homolog. Similarly, the ’552 patent application was not limited to rabeprazole until over two years after the ’013 patent application had been filed. Defendants have not asserted indistinctness as between any claims of the ’552 application and the ’013 application other than rabeprazole and its ethyl homolog. Indeed, there

is no overlap between the applications; neither application claims a genus including compounds within the other. When the applications are viewed in their entireties, they do not appear to be directed to patentably indistinct subject matter; and defendants have failed clearly to establish otherwise.

13. Even if a provisional double patenting rejection might have issued in the '552 application, because of the existence of the ethyl homolog claim of the '013 application, the level of materiality of a fact that might generate such a consequence is low. The provisional obviousness-type double patenting rejection is a temporary and routinely surmountable rejection.

At the relevant time, MPEP § 804 stated:

When two or more pending applications of (1) the same inventive entity, (2) the same assignee, or (3) having at least one common inventor, contain conflicting claims which are not patentably distinct, a “provisional” double patenting rejection of either the same or obviousness-type should be made in each application. Such a rejection is “provisional” since the conflicting claims are not, as yet, patented.

(PTX 31, MPEP § 804, 5th Ed., Rev. 8 at 800-4 (May 1988)). When a patent application flagged with a provisional rejection is ready for allowance, the MPEP § 804 stated:

If the “provisional” double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the “provisional” double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent.

(Id.) As Teva’s patenting expert testified, provisional double patenting rejections are withdrawn when one co-pending application is ready for allowance, and the applicant does not even have to respond to the provisional rejection in that application. (Stoner Dep. 255-58.)

14. Thus, even assuming that the possibility of a provisional double-patenting rejection would have rendered the existence of the '013 application information that a reasonable patent examiner dealing with the '552 patent would have considered “important in deciding whether to allow the application to issue as a patent,” Pro-Mold & Tool Co., 75 F.3d at 1575 – since a provisional rejection of this kind would be a step that would at least temporarily affect the issuance of the patent – the level of materiality would be too low to support, by itself, an inference of intent to deceive. A reasonable patent applicant would not regard a provisional double-patenting rejection as sufficiently problematic that the desire to avoid it would create a temptation to risk engaging in potentially fatal improper conduct, and there is no basis in this case for concluding that Eisai’s thinking was otherwise.<sup>15</sup>

15. The materiality of co-pending applications was addressed by the Federal Circuit in Dayco, 329 F.3d 1358, and Akron Polymer Container Corp. v. Exxel Container, Inc., 148 F.3d

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<sup>15</sup> The Federal Circuit Court of Appeals has held that “an application was highly material to the prosecution of an application, where it could have conceivably served as the basis of a [nonprovisional] double patenting rejection. Dayco, 329 F.3d at 1365, citing Akron Polymer Container Corp. v. Exxel Container, Inc., 148 F.3d 1380, 1382 (Fed. Cir. 1998) (internal quotation marks and brackets omitted). Yet that Court has also noted that, even when an application is subject to such a nonprovisional double-patenting rejection – in other words, when the claims of the co-pending application *are* patentably indistinct and have *already issued* as a patent by the time the subject application is due for approval – the applicant still is not “in an inescapable box” of being unable to obtain allowance of the pending claims. In re Longi, 750 F.2d 887, 894 (Fed Cir. 1985). It is “well-established” that a “patent may still issue if an applicant faced with such a [double-patenting] rejection were to file a terminal disclaimer under 35 U.S.C. § 253.” Id. (citations omitted). (Further, Eisai points out that, in such a scenario, it could simply have abandoned the ethyl homolog claim, if that claim’s existence came to be the only impediment to rabeprazole’s patentability.) Defendants have failed to show that the '013 application claims could have served as a basis for the nonprovisional double-patenting rejection of the '552 application. Moreover, as the consequences of even a *nonprovisional* double-patenting rejection were well known not to be fatal, the possible motive of avoiding a *provisional* rejection does not by itself support an inference of deceptive intent in this case.

1380 (Fed. Cir. 1998). In both cases, the Court of Appeals found the copendency of certain commonly related, commonly prosecuted applications material, although in both cases, the Court found no basis for finding inequitable conduct on this ground. Dayco, 329 F.3d at 1366; Akron Polymer, 148 F.3d at 1384.

16. As plaintiff argues, both cases are potentially distinguishable from the instant case. (See Plaintiff's Proposed Findings of Fact and Conclusions of Law ¶¶ 114-118.) However, the Court is reluctant to conclude that the co-pendency of a closely-related, even if not patentably indistinct, application would be altogether immaterial to a reasonable patent examiner. Patent disclosures, especially in highly technical fields, are often very complex; examiners with different technical backgrounds or levels of understanding may differ when evaluating relevant prior art. See, e.g., Dayco, 329 F.3d at 1368. Any reasonable patent examiner – indeed, any reasonable professional – would be interested to know that another application was pending, on behalf of the same applicant, that involved similar compounds with similar properties, and would wish to compare notes with the examiner in the other case. Arguably, such a desire on the part of the examiner to supplement her knowledge and avoid inconsistent results, (see D. Proposed Findings and Conclusions ¶¶ 228, 238), does not meet the standard of “importan[ce] in deciding whether to allow the application to issue as a patent.” A finding of immateriality, however, would have undesirable consequences. The burden on patent applicants of advising the examiner of a closely-related pending application is slight – no more than the burden on plaintiffs filing lawsuits in this Court of noting the existence of “related cases.” There is no reason why an applicant should not be encouraged to be forthcoming about such matters, and the routine disclosure of such applications would produce a real gain to the efficiency and accuracy

of the work of the PTO.

17. It is unnecessary to decide whether the mere fact of the '013 application's concurrent existence was material in itself. Here, the argument for materiality is heightened by the fact that Eisai failed to disclose to Examiner Fan, who was processing the '552 application, not merely the fact of the co-pending '013 application, but the actions taken by the examiner processing that application.

18. The Federal Circuit has held that "a contrary decision of another examiner reviewing a substantially similar claim" was material information, noting that "[a]lthough examiners are not bound to follow other examiners' interpretations, knowledge of a potentially different interpretation is clearly information that an Examiner could consider important when examining an application." Dayco, 329 F.3d at 1368. The parties disagree about whether the '013 rejections can be considered "contrary" to any decision of Examiner Fan.<sup>16</sup>

19. Defendants allege that the April 1989 rejection in the '013 prosecution was material to the '552 application. But the portion of the rejection finding claimed compounds including the ethyl homolog to be anticipated by Junggren would not have been material in the '552 prosecution, as the '552 application's claims by design, via the proviso, did not structurally

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<sup>16</sup> Defendants interpret Dayco as holding that the mere issuance of a rejection in a co-pending, "close[ly] similar[]" application is material to the prosecution of a given application, "regardless of the reason for the rejection." (D. Proposed Findings and Conclusions ¶ 236.) In that case, however, the trial court had determined, and the appellate court did not question, that the co-pending application in which rejections had issued involved "identical subject matter" to that of the disputed application. Dayco, 329 F.3d at 1367. As discussed, this Court does not find such identity between the subject matter of the '552 and '013 applications, and thus it declines to resolve whether the mere fact of the '013 application's rejections was material to the '552 prosecution based on Dayco. Even if it were, the Court's conclusion of no inequitable conduct would remain unchanged for the other reasons discussed herein.

overlap with the '013 application claims. Defendants do not contend that there is any actual basis for finding the '552 application claims to have been anticipated by Junggren, and they do not dispute that Fan herself had the Junggren reference before her.

20. The portion of the '013 examiner's April 1989 rejection finding obvious certain non-ethyl homolog claims based, in part, on Byk Gulden's teaching of trifluoromethyl substituents on the benzimidazole ring, on the other hand, was at the time at least nominally material in the '552 prosecution. The '552 application at the time still included claims – not the rabeprazole claims – that allowed for such fluorinated substituents. While Fan had at that point already rejected the '552 application claims as *prima facie* obvious, she does not appear to have considered Byk Gulden as a basis; thus, the '013 patent examiner's decision arguably could be viewed as “contrary” to hers. Additional bases for finding obviousness could have “strengthened” Fan's obviousness rejection. (See D. Proposed Findings and Conclusions ¶¶ 231, 246.) However, this theory of the materiality of this '013 application rejection is effectively academic in this litigation, as the '552 application was subsequently amended to exclude the claims allowing for fluorinated benzimidazole substituents; and defendants do not contend that this particular Byk Gulden citation would have strengthened an obviousness rejection of rabeprazole over Eisai's subsequent showing of unexpected results.

21. Defendants next argue that the December 1989 and two later, substantively identical rejections in the '013 prosecution were material in the '552 prosecution, because they cited bases for obviousness rejections of the at least somewhat similar ethyl homolog that were not cited by Examiner Fan and that, presumably, could have strengthened her rejection of the rabeprazole claims even in the face of Eisai's showing of unexpected results. Two of these bases consisted



of combinations of teachings involving Byk Gulden. Since the failure to disclose the Byk Gulden reference altogether is cited by defendants as proof of inequitable conduct, the materiality of Byk Gulden will be treated separately below.

22. Another portion of the December 1989 and subsequent rejections of the '013 application addressed Eisai's assertion in that prosecution that Junggren "contains identical substituents in the 3- and 5-positions [of the pyridine ring]" while "in the claims of the present application, the 5-position . . . is always . . . unsubstituted, while the 3-position contains methyl." (DTX 103 at DRLRAB 2507.) The '013 patent examiner stated that "Junggren . . . is not committed just to the symmetrical substituents," and he cited specific examples disclosed in Junggren of asymmetrically substituted compounds. (PTX 16 at DRLRAB 2630-33). Defendants contend that this observation "contradicted" a patentability argument Eisai had made in the '552 prosecution and therefore was "highly material" to that prosecution. (D. Proposed Findings and Conclusions ¶ 242.) As discussed, this contention does not apply the proper standard of materiality, and the '013 examiner's rejection involving his observation about Junggren's asymmetrical compounds was not directly contrary to any decision of Fan's in the '552 application. In fact, Fan had already issued an obviousness rejection of the rabeprazole claims based on Junggren by the time the '013 examiner issued his obviousness rejection of the ethyl homolog citing asymmetrical compounds in Junggren. The content of a disclosed prior art reference is presumed to be before the examiner, Li Second Family, 231 F.3d at 1378-79, and in this case the asymmetrically-substituted compounds cited by the '013 examiner were specifically

disclosed as examples in Junggren.<sup>17</sup> (See PTX 16 at DRLRAB 2631; PTX 7, U.S. Patent No. 4,255,431 at col. 9.)

23. Yet regardless of whether the rejections of the '013 application were strictly contrary to any decision taken by Examiner Fan with respect to the '552 application, this Court would be inclined to conclude "there is a substantial likelihood that a reasonable examiner would have considered [this] information important to" deciding whether to allow the '552 patent – even if ultimately to reinforce a decision of patentability. Pro-Mold & Tool Co., 75 F.3d at 1575; 37 C.F.R. § 1.56 (1987). Given the duty of candor that lies on patent applicants and their attorneys, there is no reason that patent rights should be tested by long-after-the-fact analyses in courts of law of the mutual relevance of particular, highly technical and fact-specific actions taken by examiners on arguably related applications. Such determinations are best made by the examiners themselves, for reasons of competency and efficiency, and that can only happen if patent examiners are advised of the existence of related patent applications, or at a minimum of their fellow examiners' actions with respect to such applications.

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<sup>17</sup> The '013 application examiner's rejections of Eisai's asymmetry arguments in the '013 application may have been material by the newer standard defendants invoke. While Fan had not raised novelty as an issue by that point, Eisai nevertheless in its March 1989 response to the first '552 application rejection asserted that the specific alkoxyalkoxy compounds being cited by Fan – Example 27 of Junggren and Examples 156 and 157 of GB '523 – were symmetrically substituted, in contrast to some of the then pending '552 application claims, rendering Eisai's claims purportedly novel. Novelty is an argument for patentability, see 35 U.S.C. § 102, even if, at this particular point of the '552 patent prosecution, the argument was inapposite. Conceivably, learning of the '013 application rejections could have prompted Fan to reevaluate the novelty of the '552 application claims. (See D. Proposed Findings and Conclusions ¶ 231.) (It should be noted, however, that the parties do not disagree on rabeprazole's ultimate novelty.) It is unnecessary to determine materiality on the more recent standard, however; as will be discussed, the Court does not find that Eisai failed to disclose the fact of the '013 application rejections to Fan with the requisite intent to deceive.

24. It is unnecessary on the present facts, however, to determine whether defendants have proved any materiality with respect to the co-pending ethyl homolog application and its rejections by clear and convincing evidence, since in any event, as discussed below, the Court finds that plaintiff has not proven the other requisite of inequitable conduct: an intent to deceive, by clear and convincing evidence.

**C. Intent to Deceive**

25. The Court finds that defendants have failed to prove by clear and convincing evidence that Crawford, Taniguchi or anyone else substantively involved in the prosecution of the '552 application intended to deceive the PTO into granting the rabeprazole patent by withholding information about the co-pending patent application from Examiner Fan.

26. As discussed above and in relation to the Byk Gulden reference, defendants have not proved that any of the information about the '013 application was of the highly material nature appropriate to support an inference of deceptive intent.

27. The only evidence that Eisai actually worried that information about the ethyl homolog claim would endanger the fate of the '552 application relates to the faxed exchange between Miyazawa and Taniguchi regarding Miyazawa's presentation before a pharmaceuticals industry trade conference. Both individuals testified – even if Taniguchi protested a bit much (3/8/07 Tr. 637:7-8) – that their concern centered on possible adversarial action by Hässle, whose Junggren patent generically discloses the ethyl homolog, or other competitors somehow to impede the '552 patent prosecution, but that they believed that rabeprazole was patentable.

28. Although Taniguchi's claim that he never considered the potential effect of Miyazawa's presentation on the '552 patent application is less than credible, the Court rejects

defendants' strained inference that the exchange with Miyazawa confirms that Taniguchi deliberately withheld information about the '013 application from the patent office. The information that Taniguchi directed Miyazawa not to present went well beyond information relating to the ethyl homolog. Moreover, the likelihood that information presented at a technical conference in Japan would reach the PTO in the United States appears extremely remote, making it unlikely that Taniguchi's primary motivation in addressing Miyazawa's presentation had to do with an effort to deceive the PTO, about the ethyl homolog or anything else.

29. In any event, the ultimate credibility of Taniguchi's claim that the separate prosecutions of the two applications was not a nefarious scheme to defraud the patent office is supported by the tenuousness of the strategy defendants attribute to Eisai. Defendants assert that Eisai deliberately withheld information about the ethyl homolog from the PTO, despite the fact that Eisai filed a patent application with the PTO that covered the ethyl homolog. It is undisputed that the two applications should have been expected to be, and in fact were, assigned to examiners within the same art unit. (3/6/07 Tr. 342:24-343:5.) When a new application arrived in an art unit, the supervisory examiner would review it in order to assign it to an examiner. (3/13/07 Tr. 777:2-18.) Both the '552 application and the '013 application quite likely could have been assigned to the same examiner. The strategy of filing a co-pending application that, by defendants' hypothesis, posed serious risks of undermining the chances of patenting a commercially significant drug – in the hope that the applications would be assigned to different examiners, who would never mutually recognize that seemingly related applications, with similar titles and identical inventors, had been filed by the same entity, and that the examiners would never discuss issues that came up in their respective prosecutions – seems

implausibly risky. If Taniguchi believed that the disclosure of information about the ethyl homolog would undermine the patentability of rabeprazole, it would seem far more logical that he would simply have declined to pursue a patent for the former compound.<sup>18</sup> By a preponderance of the evidence, the Court finds it quite unlikely that Eisai filed the '013 application intending to conceal its existence and related developments from the examiner of the '552 application in the same art unit during the same time period.

30. The Court further finds by a preponderance of the evidence that neither Taniguchi nor Crawford sought to conceal the existence of the '013 application to avoid a possible provisional double patenting rejection. As explained above, the risk of such a provisional rejection to Eisai's goal of patenting rabeprazole was insufficiently great, and the information therefore insufficiently material, to infer that these Eisai actors intended to engage in deceptive conduct that could later invalidate any patent achieved, and (with respect at least to U.S. patent attorney Crawford) that could result in loss of reputation and professional discipline. The Court credits Crawford's testimony that the '013 patent application was not a priority for him, and that he paid relatively little attention to its prosecution. (3/6/07 Tr. 296:19-298:23.) There is no countervailing evidence suggesting that he had any reason to identify the '013 application as a matter that had any particular bearing on the patentability of the '552 application claims, which he believed were more significant to his client and which had been filed many months earlier.

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<sup>18</sup> Eisai believed it would gain from patenting the ethyl homolog, because such a patent might serve to "block" the market for rabeprazole against competitors' manufacturing of a competing product. (3/8/07 Tr. 606:8-18.) Such a fact, however, is not reason enough to infer that Eisai would gamble on presenting the PTO with information about the ethyl homolog that, by defendants' hypothesis, Eisai believed would critically endanger chances of patenting the far more promising rabeprazole if it came to the attention of rabeprazole's examiner.

31. With respect to the various rejections of the '013 application, as opposed to its mere existence, the question is closer, because of the increased potential materiality of the '013 application once substantive rejections began to issue, and because rejections issued several times. Nevertheless, the Court finds no clear and convincing evidence that these rejections would have appeared so obviously important to a reasonable examiner's decision whether to allow the '552 application to issue as a patent as to support an inference that Taniguchi or Crawford or any Eisai actor concealed the rejections' occurrence with an intent to deceive.

32. With the benefit of hindsight, and as a policy matter, it would seem preferable for Eisai to have advised the PTO from the outset that it was submitting two related patent applications. Had it done so, the respective examiners would have been able to confer and to monitor each other's actions, and Eisai would not have been subject to criticism or suspicion. However, even assuming *arguendo* that these rejections were somewhat material, the practical reality by the time of their occurrence was that the two applications appeared to be on different tracks. In particular, the discussion of structural similarity between the Eisai compounds and those claimed in Junggren – the basis of the '013 rejections – was water over the dam in the '552 prosecution. By the time of the December 1989 office action in the '013 application, the '552 application examiner had already rejected the rabeprazole claims as *prima facie* obvious and expressly found “unpersuasive” and incomprehensible Eisai's March 1989 asserted distinction based on asymmetrical substitution. Crawford and Examiner Fan had agreed that Eisai would submit data from an actual comparison of the claimed compound and the closest prior art (Example 27 of Junggren, if the claim was limited to rabeprazole) in an effort to show unexpected properties. By the time it came up in the '013 office action, any issue about

substitution symmetry was no longer in the forefront of the '552 application. At that point, the fate of the '552 application appeared to hinge, from the viewpoint of any reasonable observer or participant, on rabeprazole's pharmacological properties. The Eisai team's focus on unexpected results, and its well-founded belief that this was also the focus of Examiner Fan, renders dubious the inference that Eisai actors deliberately withheld the '013 examiners' conclusions from Fan for fear of endangering rabeprazole's patentability, rather than simply because the issues involved in the two applications reasonably appeared to be quite different.

33. For these reasons, as well as based on its assessment of the demeanor and general credibility of the witnesses (especially Crawford), the Court credits the testimony of Crawford and Taniguchi that they did not deliberately withhold information about the '013 rejections in order to deceive the PTO, and that they simply did not identify the '013 rejections as matters making a potential difference to the prospects for obtaining a patent for rabeprazole. (See 3/5/07 Tr. 168:20-170:3, 192:19-212:25; 3/8/07 Tr. 600:17-604:8, 607:10-608:22, 610:11-21, 617:2-10; 3/12/07 Tr. 668:22-669:3, 673:9-16, 686:17-687:22.)

34. The credibility of the Eisai witnesses, and the lack of intent on the part of Eisai to deceive the PTO, is further supported by evidence that Taniguchi and Crawford not only disclosed the existence of Junggren – a key basis of rejections in the '013 application – in the '552 application itself, but also specifically identified Example 27 of that reference as relevant prior art. This evidence is particularly significant to the extent that defendants contend that the '013 rejections were material because of their indications about Junggren. It is not plausible that plaintiffs' patenting agents would conspire to withhold information about Junggren from the PTO, when they had themselves disclosed this very reference. Taniguchi and Crawford also

exercised good faith in providing substantial other prior-art disclosures, as described above, in its prosecution of the rabeprazole patent.

### **III. Nondisclosure of Byk Gulden**

#### **A. Materiality**

35. Whether considered as an independent ground or as a basis in connection with the nondisclosure of the '013 rejections, the Court finds that defendants have not shown by clear and convincing evidence that the Byk Gulden patent was material.

36. Defendants's numerous arguments regarding Byk Gulden boil down to the theory that the reference was material because a reasonable examiner of the '552 application could have used it to issue "a new and far stronger *prima facie* obviousness rejection."<sup>19</sup> (D. Proposed Findings and Conclusions ¶ 251; see Smith Aff. ¶ 155.) One reason Byk Gulden could have triggered such a consequence, defendants contend, is that it noncumulatively provided a basis to learn of asymmetrically-substituted compounds bearing a methoxyethoxy at the pyridine ring's 4-position. (See D. Proposed Findings and Conclusions ¶¶ 249, 251.) The evidence, however, compels the conclusion that, to the extent that the asserted relevance of Byk Gulden is based on any teaching of this pyridine-ring pattern, Byk Gulden is cumulative of Junggren or of Junggren combined with Beecham – prior art references that Eisai had disclosed to the '552 examiner – and therefore is not material. Indeed, Teva's expert, Stoner, conceded that Byk Gulden taught

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<sup>19</sup> Defendants also argue that Byk Gulden was material because it was "prior art inconsistent with arguments Eisai made" for the patentability of the '552 application claims. (D. Proposed Findings and Conclusions ¶ 245.) As already discussed in relation to the purportedly materiality of the '013 application rejections, this contention applies the wrong materiality standard. To the extent that the new standard could be considered, this Court nevertheless finds that Byk Gulden was not material, because, as will be discussed, it is either cumulative or does not teach the information defendants contend that it does.



nothing more in terms of asymmetry or a 4-position methoxyethoxy than was already disclosed by references already before Examiner Fan. For example, Stoner admitted that if the 4-position substituent of Example 27 of Junggren (i.e., methoxyethoxy) were substituted into the 4-position of Example 7b of Beecham, one would achieve the same result as by combining Byk Gulden reference with Junggren. (Stoner Dep. at 245:5-12.) Stoner further admitted:

Q. And an Examiner making a prima facie rejection would be equally able to combine Junggren and Beecham as they would be able to combine Junggren and the Byk Gulden reference, correct?

A. If the Examiner appreciated it, yes.

(Stoner Tr. 247:6-12). Moreover, Junggren, which was before Fan, specifically and apparently disclosed asymmetrically substituted compounds. (See PTX 16 at DRLRAB 2631; PTX 7, U.S. Patent No. 4,255,431 at col. 9.) Being merely cumulative in this respect, Byk Gulden therefore is not material.<sup>20</sup> Litton Sys., 87 F.3d at 1570.

37. Defendants further argue that Byk Gulden was material to the issue of obviousness of the '552 application claims, because it specifically taught rabeprazole's methoxypropoxy 4-position pyridine ring substituent. Defendants have failed to prove by clear and convincing

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<sup>20</sup> This lack of materiality is corroborated by the fact that, as described above, when the claims of the '013 application were amended in 1996 to deviate from a compound having a methoxyethoxy substituent at the 4-position of the pyridine ring, the '013 examiner appeared to recognize that the methoxyethoxy compounds of Byk Gulden did not support an obviousness rejection. Thus, the citation of Byk Gulden's methoxyethoxy compounds against the '013 application, which at the time encompassed compounds having a methoxyethoxy substituent at the 4-position of the pyridine ring, does not by itself support the conclusion that these cited compounds had any importance to other compounds like rabeprazole lacking such a substituent. Even if Byk Gulden were taken as somewhat material, based on some teaching relating to rabeprazole's pyridine-ring substituents, the low practical materiality of any such teaching to a prosecution chiefly premised on rabeprazole's unexpectedly superior properties, for reasons already discussed, would not support an inference of a deceptive intent.

evidence that Byk Gulden was material based on this disclosure. Indeed, as discussed in this Court's findings of fact, Byk Gulden does not in fact contain this teaching. Thus, Byk Gulden was not material to the '552 patent application on the basis of the methoxypropoxy-related teaching defendants assert.

**B. Intent to Deceive**

38. Defendants have failed to prove by clear and convincing evidence that Crawford or Taniguchi intended to deceive the PTO by failing to disclose the Byk Gulden reference. They have not shown sufficient materiality that an inference of deceptive intent would be appropriate. That Eisai had tracked the development activities of the company owning the Byk Gulden patent (see, e.g., DTX 90T at ECL 129200), and presumably was therefore aware of the Byk Gulden reference's existence, far from indicates that those prosecuting the '552 application harbored defendants' view that the reference was greatly and harmfully material and thus must fraudulently have concealed it. The fact that Eisai's responses to rejections in the '013 application during the relevant time never addressed the citation of Byk Gulden supports the conclusion that neither Taniguchi nor Crawford was alerted to the reference's importance to the '552 application in general, much less to the (unpersuasive) rabeprazole-related interpretations asserted by defendants. A conclusion that the Byk Gulden reference lacked materiality in the context of the rabeprazole application – and that no relevant Eisai actor can reasonably be presumed to have believed otherwise – is also consistent with defendant Teva's failure to rely on the reference or on any of the '013 examiners' citations of it as a basis for asserting invalidity of the '552 patent in opposition to Eisai's summary judgment motion. See Eisai II, 2006 WL 2872615.

#### IV. Selection of Data for the Fujisaki Declaration

##### A. **Materiality**

39. There is no dispute that the Fujisaki Declaration, constituting Eisai's response to an obviousness rejection of rabeprazole by a showing of rabeprazole's pharmacological properties, was highly material. Defendants contortedly contend that the submission was misleading, because it unnecessarily contained favorable comparisons to two non-prior-art compounds, and because, as long as Eisai was unnecessarily comparing non-prior-art compounds, it should have compared the non-prior-art ethyl homolog. (See D. Proposed Findings and Conclusions ¶¶ 257-260.) The Court concludes that defendants have failed to prove by clear and convincing evidence that the Fujisaki Declaration was misleading for these reasons.

40. The Fujisaki Declaration provided Fan with precisely the comparison she was seeking: the comparison between rabeprazole and prior art compound Example 27 of Junggren. Defendants do not now contend that the experimental data described in the Fujisaki Declaration in themselves were in any way falsified or defective. Nor do they dispute that the data submitted actually demonstrated rabeprazole's superiority over the prior art compound Fan had flagged. They provide no authority for their implicit proposition that submission of unnecessary but accurate data, where necessary data are actually and accurately submitted, is legally improper.<sup>21</sup> The submission of additional data accurately showing rabeprazole's superiority to other,

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<sup>21</sup> Defendants further argue that "the inclusion of Compounds 3 and 4 in the Fujisaki Declaration was itself a misrepresentation that these compounds were in fact in the prior art." (D. Proposed Findings and Conclusions ¶ 258.) Even accepting the argument *arguendo*, the supposition fails to disturb the Fujisaki Declaration's uncontested showing that rabeprazole exhibited unexpectedly superior properties. In any event, it is difficult to see why an inaccurate statement that *expanded* the category of prior art could be the product of an intention by a patent applicant to deceive the PTO.

irrelevant compounds is neither material nor deceptive. Therefore, the Court concludes that inclusion of data on two non-prior-art compounds, Compounds 3 and 4, in the Fujisaki Declaration, was not misleading.

41. Defendants' contention that Eisai should have included pharmacological data about the ethyl homolog in the Fujisaki Declaration is similarly rejected, as it is undisputed that the ethyl homolog was not a prior art compound. Because the ethyl homolog was not prior art to rabeprazole, rabeprazole's performance relative to the ethyl homolog was legally irrelevant to its patentability and need not have been demonstrated in the Fujisaki Declaration. See Norton v. Curtiss, 433 F.2d 779, 796 (C.C.P.A. 1970) (Norton's failure to prove that the undisclosed fibers "were in fact prior art fibers" was "fatal to Norton's case"); Envtl. Design, Ltd. v. Union Oil Co., 713 F.2d 693, 698 (Fed. Cir. 1983) ("The disclosure not being prior art, it would not have been material to the patentability of the Beavon process."); Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 940 (Fed. Cir. 1990) ("Since the Viatron 21 device was not prior art, it was not material to patentability."); Ex Parte Westphal, 223 U.S.P.Q. 630, 633 (B.P.A.I. 1983) (data for non-prior-art compounds are "irrelevant" to the patentability of the claimed invention, and there was no requirement to include those data in the Rule 132 Declaration).

42. Indeed, Teva's patent expert, Stoner, did not believe data for the ethyl homolog needed to be in the Rule 132 Declaration. (Stoner Dep. 250:19-251:10.) Defendants' expert Smith also testified that an applicant has no obligation to submit comparisons with nonprior art, as such comparisons are "totally irrelevant" to the question of a given claim's patentability. (3/12/07 Tr. 743:14-744:4.) Further, just as defendants fail to provide any authority for their implicit proposition that submission of unnecessary but accurate data is legally improper, so they

fail persuasively to support their proposition that such an unnecessary submission somehow creates a legal duty to submit further unnecessary data. (D. Proposed Findings and Conclusions ¶ 26.) Accordingly, the Court concludes that omission of ethyl homolog-related data did not render the Fujisaki Declaration misleading.

**B. Intent to Deceive**

43. There is no clear and convincing evidence that Crawford, Taniguchi, or anyone acting on behalf of Eisai intended to deceive the PTO by the selection of data for disclosure in the Fujisaki Declaration. That Eisai may knowingly have omitted data about the ethyl homolog even as it included data on two non-prior-art compounds does not create an inference of such an intent, absent any factual basis for a finding of a deceptive intent. See, e.g., Atofina, 441 F.3d at 1001-02.

44. Defendants attempt to make much of the evidence that Eisai internally possessed data presumably permitting a pharmacological comparison between rabeprazole and the ethyl homolog, and that – based on, at least, the evidence of the faxed exchange between Taniguchi and Miyazawa – Eisai actors may have harbored some concern about the public disclosure of its data on the ethyl homolog. (See D. Proposed Findings and Conclusions ¶¶ 260-262.) Even if it were found that Eisai did possess such data and did harbor such concerns, however, those facts would still not change the underlying fact that the ethyl homolog was not a prior art compound of rabeprazole. No matter how much internal data it possessed about the ethyl homolog or how worried it was about potential exposure of that data, therefore, Eisai was, as discussed, under no legal duty to disclose that data in the Fujisaki Declaration. Eisai's deceptive intent cannot be inferred from even a knowing decision to omit, when it had no duty to disclose the information it

is accused of omitting.

**V. Balancing**

45. Even if a court finds that the patentee failed to disclose material information to the PTO and acted with deceptive intent, the court retains discretion to decide whether the patentee's conduct is sufficiently culpable to render the patent unenforceable. Kemin, 464 F.3d at 1346.

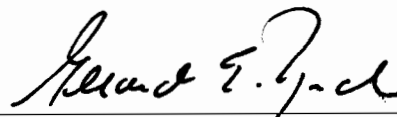
46. The '552 application is a valid patent. The parties agree that the drug product covered by the patent has therapeutic properties and is a successful product for Eisai. The nondisclosures alleged by defendants, even if material, and even if perpetrated with deliberateness, would not justify the extreme sanction of holding unenforceable the valid rabeprazole patent. The withholding of such information could have had little or no impact on the ultimate decision of the PTO to issue the patent. Under these circumstances, invalidation of the patent would not be warranted, even if the Court's conclusions with respect to materiality and intent to deceive were found to be marginally incorrect.

**CONCLUSION**

For the reasons set forth above, plaintiffs have established that defendants have infringed a valid patent. Defendants have failed to establish their defense of inequitable conduct by clear and convincing evidence. Accordingly, judgment will be entered for plaintiff.

SO ORDERED.

Dated: New York, New York  
May 11, 2007

A handwritten signature in black ink, appearing to read "Gerard E. Lynch", is written over a horizontal line.

GERARD E. LYNCH  
United States District Judge